

C. Total Maximum Daily Loads

1. Background

Section 303(d) of the Clean Water Act requires the establishment of total maximum daily loads (TMDLs), in accordance with priority rankings, for waters that are failing to meet or not expected to meet applicable water quality standards despite implementation of technology-based and other existing controls. See 40 CFR 130.7 and existing EPA guidance including "Guidance for Water Quality-based Decisions: The TMDL Process," EPA 440/1-91-001, April 1991.

TMDLs quantify the maximum allowable loading of a pollutant to a water body, and allocate this loading capacity to contributing point and nonpoint sources (including natural background, in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff) such that water quality standards will be attained. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve a single pollutant source or multiple sources (e.g., both point sources and nonpoint sources). Current regulations specify that TMDLs need to take into account critical conditions for stream flow, loading, and water quality parameters (see 40 CFR 130.7(c)(1)). Site-specific factors are thus to be reflected in the TMDL even though the TMDL process may be used to ensure that water quality goals are achieved for a waterbody segment, whole waterbody or watershed.

Under the CWA, States and Tribes are primarily responsible for developing TMDLs. EPA is required to review and approve or disapprove TMDLs developed and submitted by States and Tribes. If EPA disapproves a State or Tribal TMDL, EPA must establish such TMDL {CWA section 303(d)(2) and 40 CFR 130.7(d)}.

When applicable water quality standards cannot be attained through the implementation of controls on point sources, within the time period specified in the applicable standards or implementing regulations, States and Tribes may choose to develop TMDLs using a phased approach. The phased approach to TMDL development is intended to achieve load reductions capable of ensuring the attainment and maintenance of water quality standards. EPA expects the allocations within phased TMDLs to be based on a reasonable expectation that water quality standards will be met in a reasonable period of time.

The phased approach to TMDL development is an iterative process that provides for pollution reduction while the regulatory agency collects and uses new monitoring data and the demonstrated performance of existing controls to evaluate the TMDL and revise it as necessary. TMDLs established using the phased approach are based on best available information, sound professional judgment, and a margin of safety to account for uncertainty in available data and the anticipated relationship between controls, loading reductions and predicted changes in water quality. Such TMDLs require a monitoring plan, a schedule for installation of controls, collection of monitoring data to verify point and nonpoint source load reductions, assessment of water quality standards attainment and additional modelling, where appropriate. If standards are not attained after implementation of controls recommended by the

TMDL, the data obtained through the monitoring program should be used to revise the TMDL.

The phased approach to TMDL development recognizes that water quality standards cannot be attained immediately, but TMDLs developed on this basis nevertheless must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. When developing a TMDL using the phased approach, all known sources of pollution are considered, although specific controls on those sources may be implemented in stages. The time period associated with these stages of implementation ultimately determines when water quality standards will be met for a particular waterbody. The phased approach may provide a scheduled time frame in which to implement controls recommended by the TMDL and achieve water quality standards and may be particularly appropriate when addressing difficult water quality problems in cases when data, models and predictive tools are generally less well-developed than for water quality problems associated primarily with the discharge of a few point source pollutants into small watersheds. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination. This determination depends upon a number of factors, including, but not limited to, receiving water characteristics, persistence, behavior and ubiquity of pollutants of concern, type of remediation activities necessary, available regulatory and non-regulatory controls and individual State requirements for the implementation of water quality standards.

TMDLs established using the phased approach are the preferred approach for developing schedules of how and when water quality standards will be met in cases when data, models, and predictive tools are not yet adequate to address complex water quality situations characterized by persistent, ubiquitous pollutants and water quality impacts resulting from nonpoint sources of pollution. EPA believes that it is reasonable and appropriate in these circumstances to establish TMDLs which schedule implementation activities over a period of time. This would result in some sources achieving load allocations prior to other sources, provided that progress is being made in achieving water quality standards in accordance with the schedule established by the TMDL. Thus, for example, EPA believes it is reasonable to consider expected nonpoint source load reductions if they will result from the implementation of specific voluntary or non-voluntary controls, are specific to the pollutant of concern and the waterbody for which the TMDL is being developed. In some cases, for example, water quality standards may reasonably be expected to be met within one NPDES five-year permit cycle. In other cases the reasonable expectation of meeting water quality standards could be twenty years, following the implementation of controls on nonpoint sources such as sediment. In still other cases, the reasonable expectation of meeting water quality standards could be keyed to the implementation of other controls, (e.g. air quality standards.)

The final Guidance is not intended to comprehensively address all aspects of TMDL development and implementation of CWA section 303(d). Rather, for specific matters not addressed by the final Guidance, national regulations and guidance for the TMDL program will continue to apply to States and Tribes in the Great Lakes System (see 40 CFR 130.7 and existing EPA guidance documents such as the Technical Support Document for Water Quality-based Toxic Control, (TSD) EPA 505/2-90-001, March 1991, and Guidance for Water Quality-based Decisions: The TMDL Process, EPA 440/1-91-001, April 1991, both available in the docket).

The final Guidance does not include specific provisions for deriving nonpoint source load allocations and implementing nonpoint source controls. While general guidance on how TMDLs should consider nonpoint source loadings is provided, EPA regulations and technical guidance should be consulted for more specific information. (See, e.g., Guidance Specifying Management Measures for Sources of Nonpoint Pollution in Coastal Waters, EPA 840-B-92-002, January 1992, for a discussion of best management practices for nonpoint sources; and Technical Guidance for Estimating Total Maximum Daily Loads (TMDLs): Integrating Steady-State and Episodic Point and Nonpoint Sources, draft June, 1994, both available in the docket).

Procedure 3 specifies procedures for establishing total maximum daily loads, wasteload allocations, and load allocations. Portions of this procedure also apply to wasteload allocations calculated in the absence of a TMDLs, and to preliminary wasteload allocations for the purpose of determining the need for Water Quality Based Effluent Limits (WQBELs) under procedure 5 of appendix F. See procedure 5.A.2 and 5.F.2 of appendix F and corresponding discussion at section VIII.E.2.A and VIII.E.2.H of this document for further information.

2. Overview of Proposed Procedures 3A and 3B

a. Proposal: The proposed guidance included two distinct approaches for developing TMDLs: procedure 3A (Option A) and procedure 3B (Option B). Both options contained the same eleven general conditions applicable to TMDL development and special conditions regarding control of bioaccumulative chemicals of concern (BCCs). Options A and B were also essentially the same with respect to the development of TMDLs for open waters and connecting channels of the Great Lakes System as defined at section 132.2 of the proposed Guidance.

The main differences between the two options existed in the development of TMDLs for discharges to tributaries. These differences reflected the process by which such TMDLs were developed and the degree of specificity contained in the particular procedure. A TMDL developed for discharges to tributaries under Option A was to be based on evaluation of the basin as a whole, followed by site-by-site adjustments. In contrast, Option B focused initially on evaluating limits needed for individual point sources, with supplemental emphasis on basin-wide considerations as necessary. Specific components of Options A and B are discussed in greater detail below, and in the preamble to the proposed guidance. Readers are encouraged to review the preamble to the proposed guidance for more detailed information on the proposed Options A and B (58 FR 20928).

EPA sought comments on all aspects of both options, including the overall technical and programmatic approaches set out in each option, the consistency of each option with regard to existing national policy and program approaches, and the degree to which each option allows for integrated development of effective point and nonpoint source controls. EPA requested comments on how the options should be incorporated into the final implementation procedure and specifically asked whether all States and Tribes in the Great Lakes System should be required to adopt either Option A or B, or whether States and Tribes should be allowed to choose an approach that is consistent with one of the proposed options depending on the situation at hand. EPA also solicited comments on the option of

not providing specific TMDL provisions in the final Guidance and instead relying on existing TMDL regulations and guidance.

b. Comments: Several commenters claimed that the proposed TMDL procedures were confusing, fragmented and provided insufficient guidance on how water quality-based permit limits would be calculated. For example, many commenters found the formulas specified in Option B confusing and some suggested that certain components of the formulas were inaccurate or inappropriate.

Most commenters expressed no clear preference for either option. Many commenters advocated that the final Guidance allow States to choose either procedure 3A or 3B. Some expressed preferences for particular elements of an option. For example, one commenter suggested that the State or Tribe should be given discretion to deviate from Option A's basin-wide approach and use an area-specific approach if appropriate in a particular circumstance.

A number of commenters suggested that, although both options had merit, and/or limitations, only one should be adopted to ensure consistency throughout the Great Lakes System. Many commenters, including a number of States, preferred Option B and maintained that if a single procedure is adopted in the final Guidance, it should be Option B. These commenters believed that Option B would provide greater consistency among the States than Option A. Several commenters preferred Option B but suggested that stronger elements from Option A should be incorporated into a revised Option B. A number of commenters suggested that Option A was too burdensome.

Several commenters supported the watershed-based approach reflected in Option A. Other commenters preferred Option A but recommended specific modifications. Among the recommended changes to Option A were establishing specific requirements for mixing zones for non-BCCs. Some commenters suggested including specific formulas for calculating nonpoint source loadings.

c. Final Guidance: In response to these comments, EPA simplified the TMDL procedure in the final Guidance and clarified a number of provisions. EPA includes only one TMDL procedure in the final Guidance in response to concerns that the TMDL procedure promote consistency throughout the Great Lakes System. The final procedure 3 combines aspects of both Options A and B, and, in response to comments, includes some of the more specific provisions of both options A and B. For example, in order to promote consistency among the Great Lakes States and Tribes, EPA is retaining, with some modifications, certain mixing zone provisions for non-BCCs from option B. EPA eliminated some of the more burdensome and confusing aspects of both the proposed options. For example, in the final Guidance, the formulas in Option B are no longer included.

The final Guidance provides a greater degree of flexibility than afforded by either proposed procedure 3A or 3B by allowing States and Tribes to choose different implementation approaches while at the same time ensuring a level of consistency by requiring implementation of specific components of the procedure. For example, the final Guidance does not specify whether a State must adopt a basin-wide approach such as that in proposed Option A, or an approach like proposed Option B, which would focus initially on evaluating limits needed for individual point sources.

The final Guidance also retains the flexibility provided in the proposal. For example, although the final Guidance specifies that States and Tribes consider nonpoint source loadings, EPA has not adopted the commenters' suggestion to specify a formula to calculate nonpoint source contributions. Rather, States and Tribes are provided flexibility to evaluate such contributions and to address nonpoint source contributions through existing programs.

The final Guidance retains the eleven general conditions and the separate provisions for open waters of the Great Lakes System and tributaries, with certain modifications. Like both the proposed options 3A and 3B, the final Guidance requires the elimination of mixing zones for BCCs; however, the final Guidance adds a procedure to grant an exception for existing discharges of BCCs in limited circumstances. The general conditions of application and specific provisions of the final procedure 3 are discussed in detail below.

In addition, procedure 3 has been revised to include new language (section A), which authorizes the use of certain assessment and remediation plans in lieu of TMDLs whenever, in the final Guidance, a TMDL would be used as the basis for a wasteload allocation. Specifically, these assessment and remediation plans could be used in lieu of TMDLs when deriving wasteload allocations under procedures other than the "baseline" procedures in procedure 5.F.2 of appendix F, when establishing mixing zones for existing discharges of BCCs in waters not attaining water quality standards under procedure 3.C.6 of appendix F, or as an alternative to TMDLs and the intake pollutant procedures in procedures 5.D-E of appendix F when adjusting point source controls to account for intake pollutants as provided in procedure 5.D.1.c of appendix F. Thus, for example, when developing a WLA for a particular pollutant and point source, a State or Tribe would rely upon the applicable WLA established in an approved TMDL or assessment and remediation plan. If no such TMDL or assessment and remediation plan exists, the WLA would be derived using procedure 5.E.2.a or 5.F.2 of appendix F as appropriate.

Under procedure 3.A of appendix F, assessment and remediation plans may be used in lieu of TMDLs if they meet all the requirements of procedure 3, satisfy the public participation requirements applicable to TMDLs, and are approved by EPA under 40 C.F.R. § 130.6 as meeting these requirements. Once approved by EPA, the assessment and remediation plans will function as updates to State or Tribal continuing planning processes, which may include, among other things, TMDLs and areawide waste management plans under section 208. When seeking EPA approval of these assessment and remediation plans, States and Tribes must certify that the requirements of procedure 3 are met. Procedure 3.A also authorizes the use of qualifying assessment and remediation plans, such as Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs), under section 118(c)(3) & (4) of the CWA.

The TMDL process is an important planning tool that helps identify water quality problems and recommends solutions that link the development and implementation of control actions to the attainment of water quality standards. The objective of a TMDL is to allocate allowable loads of a particular pollutant among difference sources of that pollutant so that the appropriate control actions can be taken and water quality standards achieved. As discussed in section VIII.C.1 above, when water quality

standards cannot be attained immediately, TMDLs may be developed under a phased approach if appropriate. While TMDLs are the preferred mechanism for addressing water quality impairments, particularly where nonpoint source contributions are significant, EPA recognizes that other mechanisms can employ the same type of analysis and obtain the same results as formal TMDLs. EPA also acknowledges the comments, particularly of States, that identify comparable planning tools. In particular, as described in section I.D.4 of this document, the States and EPA Regional offices in the Great Lakes basin have undertaken significant assessment and remediation planning efforts through the development of RAPs and LaMPs. Some States may undertake similar efforts through water quality management plans under sections 208 of the CWA. Accordingly, the final Guidance specifically recognizes that assessment and remediation plans other than TMDLs can be used with comparable water quality effect, provided that they contain certain basic elements. In other words, EPA expects that assessment and remediation plans developed and approved under procedure 3.A of appendix F can function in lieu of a TMDL for water quality decisionmaking in the Great Lakes System because such plans, at a minimum, will assess the sources causing or contributing to a particular water quality impairment, identify remediation activities that are reasonably expected to result in nonpoint source load reductions as necessary, in combination with point source controls, to achieve water quality standards within a reasonable period of time, incorporate a margin of safety, and establish wasteload allocations for point sources that are consistent with these water quality objectives. Procedure 3.A also provides that any part of an assessment and remediation plan that also satisfies one or more requirements under CWA section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. If a State or Tribe submits for EPA approval an assessment and remediation plan under procedure 3.A that fully satisfies the requirements for a TMDL, EPA may also approve that plan under section 303(d).

3. General Conditions of Application

As proposed, Options A and B both contained the same eleven general conditions of application for every TMDL established under the GLWQI to assure that TMDLs employed consistent methodologies, analytical approaches and assumptions. Commenters overwhelmingly supported the proposal to include a set of general conditions applicable to all aspects of TMDL development.

Language is added in the final Guidance to clarify that the general conditions also apply, where indicated, to wasteload allocations (WLAs) calculated in the absence of TMDLs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of the final Guidance.

a. General Condition 1 - TMDLs Required

i. Proposal: General condition 1 described the circumstances under which a TMDL would be required upon State or Tribal adoption or EPA promulgation of the Guidance. In the proposal, general condition 1 specified that, at a minimum, TMDLs were to be established for each pollutant for which it was determined that there is reasonable potential that a discharge will cause or contribute to an exceedance of water quality standards as determined pursuant to proposed procedure 5. As proposed, such TMDLs would need to be established in advance of the issuance of any new or

revised permit for the discharge of the pollutant, unless it was determined pursuant to the proposed procedures that a TMDL is not needed.

Proposed procedure 5 specified that the State or Tribe was to include a water quality-based effluent limit in an NPDES permit whenever a pollutant is or may be discharged into the Great Lakes System at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value. Under procedure 5, as proposed, States or Tribes would have been required to develop preliminary effluent limitations to determine if all Tier I criteria and Tier II values would be met after discharge, where there was data to develop such criteria or values. Preliminary effluent limitations were to be derived from preliminary wasteload allocations, which in turn were to be based upon and consistent with the wasteload allocation procedures defined in the proposed procedure 3. As proposed, the procedure 3 requirement that a TMDL be developed whenever reasonable potential to cause or contribute to an exceedance of water quality standards was found, and the requirement that preliminary effluent limits based on preliminary WLAs developed under procedure 3 be used to determine if there is reasonable potential, were confusing and implied a circular logic. The proposal provided, in effect, that TMDLs be developed when reasonable potential was demonstrated, and that reasonable potential be demonstrated on the basis of preliminary effluent limits, normally derived from TMDLs.

ii. Comments: EPA received numerous comments on general condition 1. A number of commenters were concerned with the perceived burden associated with developing TMDLs under the proposal and, in particular, many were concerned with the burden associated with requiring a TMDL for a waterbody in advance of issuing any new or revised permits. These commenters asserted that general condition 1 would essentially prohibit any point source discharges of a particular pollutant in the absence of a TMDL for that pollutant. The commenters contended that the effect of the prohibition would be to require TMDLs on the basis of a single discharger's "reasonable potential" to exceed standards even in waters where TMDLs would have minimal environmental benefit, and thus would be inefficient. Several commenters claimed that the existing national TMDL program requirements for identifying waters not meeting standards, and for setting priorities to develop TMDLs, are sufficient to ensure that TMDLs are developed for those waterbodies most in need.

Numerous commenters pointed out the ambiguity between proposed procedure 3 and proposed procedure 5 relating to determination of reasonable potential. Under proposed procedure 3, a TMDL was required when there was a finding of reasonable potential. However, under proposed procedure 5, a finding of reasonable potential would be based on a "preliminary wasteload allocation" prepared using the procedures set forth in the TMDL procedure. The proposal did not define "preliminary WLA."

A number of commenters suggested other circumstances that should trigger the requirement to establish a TMDL. Several commenters suggested that TMDLs be required for pollutants that have caused fish consumption advisories on the premise that waters subject to fish consumption advisories are exceeding narrative water quality criteria, if not numeric criteria.

iii. Final Guidance: General condition 1 in the final Guidance no longer specifies that a TMDL would need to be developed for each pollutant for which reasonable potential is found. Instead, TMDLs shall be established in accordance with the waterbody listing and prioritization process outlined in CWA section 303(d), 40 CFR 130.7 and existing EPA guidance. Under existing law, if existing required controls are not sufficient to attain and maintain applicable water quality standards, the waterbody must be included on the 303(d) list, which, under the regulations, is to be submitted to EPA for review and approval or disapproval. The list must include a priority ranking of listed waters and must identify those waters targeted for TMDL development as required by CWA section 303(d)(1)(A) and 40 CFR 130.7(b)(4). EPA makes this change in response to commenters' concerns about the proposal. First, the final Guidance refers back to the national TMDL program rather than creating a new trigger for TMDL development based on a finding of reasonable potential under procedure 5. This should minimize the confusion created by the proposal. The final Guidance, by referring to existing TMDL regulations, should also minimize concerns about the additional burden that might have occurred under the proposal (e.g., permitting subject to TMDL development). Changes to the proposal were also made to address concerns about the use of limited resources to develop TMDLs in waters presently attaining water quality standards but where the discharge of a particular pollutant has the reasonable potential to cause or contribute to an excursion above those water quality standards. While TMDLs for waters currently attaining water quality standards are important tools to ensure that such standards are maintained, EPA recognizes that many States and Tribes may choose to place a higher priority on restoring impaired or threatened waters and will choose to use their limited resources for that purpose. This change is intended to preserve State and Tribal discretion in establishing priorities for TMDL development and implementation.

In response to comments advocating that fish consumption advisories should trigger TMDL development EPA is developing guidance to clarify the relationship between fish advisories and section 303(d) lists. (Draft memo dated July, 1994, available in the docket). EPA believes that, absent information to the contrary, it should be presumed that fish consumption advisories demonstrate use impairments for waters designated for the uses specified in section 101(a) of the Clean Water Act, when defined by a State or Tribe to include fishing. The listing of such waterbodies on section 303(d) lists is consistent with the purpose and intent of the Clean Water Act.

General condition 1 also provides that, when water quality standards cannot be attained immediately, the TMDL must reflect reasonable assurances that they will be achieved in a reasonable period of time. For a more thorough discussion of this concept, see section VIII.C.1 above.

b. General Condition 2 - Attainment of Water Quality Standards

i. Proposal: In the proposal, general condition 2 discussed the load reductions that should be achieved through TMDLs. The first sentence of general condition 2 supplemented the provisions of proposed general condition 1 by specifying that TMDLs would also need to be developed whenever the sum of existing point source and nonpoint source (including natural background) loadings of a particular pollutant exceeds the loading capacity of the water for that particular pollutant, minus any margin of safety and minus any capacity reserved for future growth. As proposed, general condition 2

also established that a TMDL for a given pollutant must implement all criteria for that pollutant that are applicable to the waterbody in question.

ii. Final Guidance: EPA did not receive significant comments on general condition 2 as proposed. However, EPA has reorganized proposed general conditions 2 (Load Reductions), 3 (WLA Values) and 9 (TMDL Allocations) in order to present the same material in a sequence that more closely tracks the requirements of CWA section 303(d). General condition 2 is now entitled "Attainment of Water Quality Standards" and consists of a single sentence on that subject drawn from proposed general condition two. The final guidance specifies that a TMDL must ensure attainment of water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values where applicable for each pollutant or pollutants for which a TMDL is established. By including a specific reference to water quality standards in addition to criteria, the final Guidance clarifies that, under section 303(d), TMDLs must provide for the attainment of water quality standards in their entirety, and not just their criteria components.

The third sentence of proposed general condition 2 has been incorporated into general condition 3 (now entitled "TMDL Allocations") of the final Guidance. The final Guidance does not include the proposed language specifying that TMDLs be prepared if the sum of existing point source and nonpoint source loadings exceeds the loading capacity minus any specified margin of safety for a substance. This sentence was intended merely to restate existing requirements under section 303(d) of the Clean Water Act and TMDL regulations at 40 CFR 130.7, and therefore is unnecessary. In EPA's view, these provisions and other applicable requirements of the Guidance are sufficient to ensure that TMDLs developed under this final Guidance will provide for attainment of water quality standards.

c. General Condition 3 - TMDL Allocations

i. Proposal: This general condition was numbered as general condition 9 in the proposal. As proposed, this condition provided that nonpoint source load allocations must be based on existing loading rates or on anticipated increased loading rates unless a lower loading rate is expected to occur within a reasonable period of time as a result of implementation of best management practices or other control measures. It also provided that the portion of the loading capacity not assigned to nonpoint sources, or to an MOS, or reserved for future growth is allocated to point sources. Finally, it stated that, upon reissuance, NPDES permits for these point sources must include limitations consistent with the WLAs in EPA-approved or EPA-established TMDLs.

ii. Comments: Some commenters advocated that the final Guidance only allow the incorporation of nonpoint source reductions where such reductions are required by legally enforceable mechanisms to ensure that reductions from nonpoint sources are "reasonably expected to occur" within relevant time frames. Furthermore, the commenters suggested that a reasonable period for such reductions would be eight years. Another commenter supported the phased approach for load allocations because it allowed an iterative process for implementing nonpoint and point source controls.

iii. Final Guidance: As part of its reorganization of the general conditions in the final

Guidance, EPA has renumbered proposed general condition 9 to become general condition 3 in the final Guidance. As part of that reorganization, EPA has also incorporated into new general condition 3 the language proposed under the heading "Load Reductions" that defines the elements of a TMDL. EPA has also established subparagraphs within general condition 3 of the final Guidance to correspond to the discussion in general condition 3 of the elements of a TMDL, nonpoint source load allocations, point source wasteload allocations, and monitoring.

Specifically, EPA has added as subparagraph (a) the statement from proposed general condition 2 that TMDLs shall include wasteload allocations and load allocations for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant addressed by the TMDL, minus the sum of a specified margin of safety and any capacity reserved for future growth. EPA has made only minor changes to the proposed language to clarify that the nonpoint source load allocations include natural background conditions and to link loading capacity to the pollutant for which the TMDL is being developed.

Subparagraph (b) comprises the portions of proposed general condition 9 pertaining to nonpoint sources. These provisions were modified in general condition 3 only to make consistent use of the term loadings and to clarify that expectations regarding decreased loadings from nonpoint sources must be based on a reasonableness standard. The only significant comments EPA received on proposed general condition 9 addressed nonpoint source issues. EPA disagrees with the commenter's suggestion that nonpoint source reductions be considered only when such controls are required by legally enforceable mechanisms. EPA suggests that means other than legally enforceable mechanisms are available to ensure that nonpoint source reductions that are "reasonably expected to occur" within a specified time frame actually do occur. For example, funding nonpoint source controls and using the monitoring component of the phased approach to TMDL development, as described earlier in this document, are means to assure that anticipated load reductions are actually occurring. Although EPA supports the use of a phased approach to TMDL development where appropriate, EPA stresses that smaller load allocations to nonpoint sources can be used to justify larger WLAs to point sources only when the anticipated reductions in nonpoint source loadings are reasonably expected to occur.

EPA agrees with the comment that a TMDL can consider anticipated nonpoint source loading reductions. TMDLs developed using the phased approach are based on the reasonable expectation that water quality standards will be met in a reasonable period of time and that specific controls may be implemented in stages. What constitutes a reasonable period of time will vary depending upon the situation. Therefore, EPA will not specify any particular period, such as eight years. The time period associated with these stages of implementation will ultimately determine when water quality standards will be met for a particular waterbody. To the extent consistent with other applicable law concerning schedules of compliance, permits issued after the completion of a TMDL should be consistent with implementation schedules established by the TMDL.

Placed within new subparagraph (c) are the provisions in proposed general condition 9 pertaining to point source wasteload allocations and their effect on NPDES permits. Apart from including a reference to natural background in connection with nonpoint sources, these provisions are

unchanged from the proposal.

In the final Guidance, EPA added subparagraph (d) to address the monitoring issues encompassed within the proposal's discussion of anticipated decreases in pollutant loadings from nonpoint sources. Subparagraph (d) provides that, for load allocations established on the basis of (a)(iii) of general condition 3, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to verify the anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and load allocations as necessary to ensure that water quality standards will be achieved within the time period established in the TMDL. This monitoring can be performed as part of the water monitoring program established by the State (or at its election by the Tribe) under 40 CFR 130.4, which specifies development and review of TMDLs, wasteload allocations and load allocations as among the uses for such monitoring data.

d. General Condition 4 - WLA Values

i. Proposal: This general condition was numbered as general condition 3 in the proposal. As proposed, this condition specified that point sources be regulated to ensure attainment of all downstream water quality standards. Proposed general condition 3 also recognized that TMDLs developed for a particular waterbody may include WLAs for sources already covered by a TMDL of a different geographic scope. For example, a source-specific TMDL may already be in place when a basin-wide TMDL is developed. General condition 3, as proposed, provided that water quality-based effluent limits (WQBELs) in NPDES permits for a particular pollutant be consistent with the most stringent of the WLAs for that pollutant and point source included in any EPA-approved or EPA-established TMDLs. This provision was intended to assure that water quality standards will be met throughout a drainage basin, including in downstream waters.

ii. Final Guidance: EPA did not receive significant comments on proposed general condition 3. Thus, the final Guidance retains the substance of the general condition with slight modifications, but EPA has renumbered it as general condition 4 in the final Guidance to reflect EPA's decision to move proposed general condition 9 (TMDL Allocations) up to become new general condition 3 in the final Guidance.

This provision in the final Guidance, like the proposal, directs permit writers to apply the most stringent of the WLAs included in any EPA-approved or EPA-established TMDL. The final Guidance clarifies that this provision applies only when more than one approved TMDL establishes a different WLA for the same pollutant discharged by the same point source. In addition to renumbering this as general condition 4, EPA made one other change. The proposed language stating that "point sources must be regulated so as to ensure attainment of all downstream water quality standards" has been deleted in the final Guidance because it merely restated current law. Specifically, under existing CWA section 402 and 301(b)(1)(C), WQBELs in NPDES permits must ensure attainment of all applicable water quality standards, including downstream water quality standards. Under 40 CFR 122.44(d)(1)(vii), such WQBELs must be consistent with any available WLAs developed and approved pursuant to 40 CFR 130.7.

e. General Condition 5 - Margin of Safety

i. Proposal: This general condition was numbered as general condition 4 in the proposal. As proposed, this condition reiterated the requirement in CWA section 303(d) that each TMDL include a margin of safety (MOS) and described the manner in which the MOS is provided. It also reiterated EPA guidance that the MOS may be established either by setting aside a portion of the loading capacity or by using conservative modelling assumptions in deriving the TMDL.

ii. Comments: Several commenters were concerned that it would be inappropriate to leave determination of an MOS to the discretion of the permit writer. One commenter recommended that in order to facilitate basin-wide consistency and maximum environmental protection, the Guidance should implement an explicit MOS factor equal to the Criterion Maximum Concentration (CMC) value (which equals one-half of the Final Acute Value (FAV)). Other commenters advocated specifying a specific confidence level to use in modeling a MOS.

Several commenters believe that the MOS requirement is redundant given the number of conservative assumptions built into the criteria development process and into the assumptions on fate and transport.

Several commenters were concerned that including uncertainties regarding controlling pollutants from nonpoint sources into the margin of safety merely shifted the control burden to point sources without requiring EPA, States or Tribes to regulate other sources of pollution. They were concerned that a larger MOS would result in a smaller WLA, thus requiring a facility to discharge less and treat more while nonpoint sources would not be controlled.

iii. Final Guidance: Apart from minor changes to improve clarity and renumbering to reflect the overall reorganization of procedure 3.B of appendix F, the final Guidance is unchanged from the proposal. General condition 5 maintains flexibility for the State or Tribe to consider a number of factors, including case-specific conditions (e.g., availability and quality of data) in establishing a margin of safety. As indicated in 40 CFR 130.7(c)(1), the margin of safety is intended to account for uncertainty in the available data or in the actual effect controls will have on loading reductions and receiving water quality. EPA has determined that because of the need to reflect local conditions and case-specific technical considerations, it is inappropriate to specify a universal MOS factor. Although EPA recognizes the flexibility of the State or Tribe to assess available information, EPA retains the authority to disapprove a TMDL if EPA finds that a MOS is inadequate.

In response to comments that the MOS has the effect of shifting the burden of load reductions to point sources, EPA notes that the MOS requirement does not compensate for failure to consider some sources (e.g., nonpoint sources as suggested by commenters) but rather is intended to account for any technical uncertainty regarding both point and nonpoint source loading data and the effectiveness of controls. EPA acknowledges that the technical uncertainty related to nonpoint sources may in fact be greater than uncertainty regarding the effects of point sources. EPA believes that the phased approach to TMDL development provides, over time, an effective mechanism for reducing technical uncertainty

related to nonpoint sources. This reduction in uncertainty will, over time, quantify and consider relative contributions and water quality impacts and lead to appropriate levels of control for both point and nonpoint sources.

EPA disagrees with the commenters' suggestion that the MOS is redundant given the conservative assumptions built into the criteria development and into assumptions on fate and transport. The MOS, as required by CWA section 303(d), is intended to account for technical uncertainties regarding the relationship between pollutant loads and water quality. These factors are not considered in the development of criteria and thus are not duplicative of assumptions used in developing criteria. Conservative assumptions in criteria development are designed to address specific uncertainties and concerns regarding extrapolations of toxicity data to individual or population endpoints. EPA also suggests that there should not be an issue of redundancy regarding the fate and transport assumptions and the MOS. The assumption of no pollutant degradation for purposes of TMDL development is rebuttable when scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur.

f. General Condition 6 - More Stringent Requirements

This general condition was numbered as general condition 4 in the proposal. As proposed, this condition provided that States may employ section 510 of the CWA to establish TMDLs more stringent than those developed pursuant to procedure 3. The condition reiterated the reserved right of States to require more stringent controls than those required under the CWA.

EPA received no significant comments on this provision. The proposed language is modified slightly in the final Guidance to clarify that both States and Tribes may employ section 510 and to correct a typographical error. It has also been renumbered as general condition 6 to reflect the overall reorganization of procedure 3.B of appendix F.

g. General Condition 7 - Accumulation in Sediments

i. Proposal: This general condition was numbered as general condition 6 in the proposal. As proposed, this condition specified that TMDLs must be stringent enough to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life. It also specified that TMDLs consider contributions to the water column from sediments inside and outside applicable mixing zones. Although TMDLs are calculated on the basis of pollutants in the water column, the preamble to the proposal indicated that all sources of pollution, including sediment re-release of pollutants to the water column, would need to be considered in establishing TMDLs.

ii. Comments: EPA received numerous comments on this condition. A number of commenters disagreed with the proposal. Several suggested that proposed general condition 6 be deleted until EPA finalizes and implements a national sediment strategy. One commenter suggested that proposed general condition 6 be optional depending on the availability of information or, if not, that

general condition 6 should be removed entirely.

Several commenters stressed the importance of considering the release of toxics from contaminated sediments, which in many instances may result in a failure to meet water quality standards. Several commenters, while agreeing with the need to consider all sources of pollutants, including sediment release or resuspension of pollutants, believe that methodologies do not currently exist to accurately reflect the sediment re-release process. One commenter suggested that sediments should only be accounted for by concentrations measured in the water column and that any additional factors would be duplicative. Commenters recommended that EPA continue to work on National guidance for such methods and suggested that any process for developing sediment criteria should be subject to a peer review process.

iii. Final Guidance: The final Guidance retains the requirement that TMDLs reflect processes such as re-release of pollutants from sediments, because, as noted by many commenters, contaminated sediments are often a source of pollutant loading to the water column and thus may cause or contribute to an exceedance of water quality standards. However, EPA has modified this provision to clarify that such contributions should be considered only where appropriate and where sufficient data are available. EPA has renumbered this provision as general condition 7 to reflect the overall reorganization of procedure 3.B of appendix F.

EPA agrees with commenters that existing methodologies may not fully reflect all aspects of the sediment re-release process. However, EPA recently proposed its Contaminated Sediment Management Strategy (EPA 823-R-94-001) for public comment, 59 FR 44880, (August 30, 1994, available in the docket), and is continuing to develop methodologies to evaluate the sediment re-release process. The strategy proposes establishing standardized test methods to assess whether sediments are contaminated and proposes to continue supporting research on the re-release of pollutants from contaminated sediment. Under the strategy, EPA would develop new biological methods to assess the ecological and human health effects of sediment contaminants, sediment wasteload allocation models, and technologies for remediation of contaminated sediment. EPA is also working to develop chemical-specific sediment quality criteria. This process will involve review from outside parties. See 59 FR 2652, January 18, 1994 for further information.

EPA is moving forward with many of the activities described in the draft Contaminated Sediment Management Strategy and expects many of these activities to be completed in time to support State and Tribal procedures under part 132. The final Contaminated Sediment Management Strategy and associated outreach efforts will support States and Tribes in implementing general condition 6. Therefore, EPA disagrees with the comment that this condition needs to be deleted until EPA finalizes the Strategy.

Several commenters suggested that situations may exist where information is not available to determine the nature and extent of contaminated sediments' contributions of pollutants to the water column. EPA has modified the final Guidance to specify that contributions to the water column from contaminated sediments be included where appropriate. It may be considered appropriate to reflect

contributions of pollutants from contaminated sediment only where data exist regarding sediment re-release of the pollutant(s) of concern. Where such information does exist, however, the TMDL must account for contributions from contaminated sediments.

In the final Guidance, EPA has reversed the order of the two sentences appearing in proposed general condition 6 in order to emphasize that contaminated sediments can be sources of pollutants to the water column and that TMDLs need to account for contributions from that source. As in the proposal, in addition to specifying that sediment re-release of pollutants shall be considered where appropriate, the final Guidance provides that TMDLs must be sufficiently stringent so as to prevent injurious accumulation of the pollutant of concern in sediments, because such injurious accumulations would represent exceedances of water quality standards (at a minimum by impairing a designated aquatic life use).

h. General Condition 8 - Wet Weather Events

i. Proposal: This general condition was numbered as general condition 7 in the proposal. As proposed, this condition recognized that some of the TMDL development procedures may be appropriate for wet weather events (e.g., nonpoint sources, storm water discharges, and combined sewer overflows). However, the proposed TMDL implementation procedures did not include explicit procedures detailing how to develop TMDLs to reflect wet weather events; rather it left maximum flexibility to the States and Tribes on how best to accomplish this. The preamble discussion of proposed general condition 7 interpreted that condition as providing that loadings from wet weather events be included in establishing TMDLs, but the proposal itself was silent on this point.

ii. Comments: Several commenters suggested that proposed general condition 7 needed to clarify that all TMDLs must include consideration of necessary waste load allocation and load allocations for wet-weather pollutant contributions. Another commenter pointed out that certain POTWs face compliance difficulties as a result of wet weather flows. The commenter suggested that these factors, which are beyond the control of the POTW, be considered in developing permit limits. Several commenters asserted that wet weather contributions cannot be accurately estimated and therefore suggested this general condition be removed all together.

iii. Final Guidance: The final Guidance retains the proposed language on wet weather flows with minor modifications and an additional sentence for clarification purposes. This provision has been renumbered in the final Guidance as general condition 8 to reflect the overall reorganization of procedure 3.B of appendix F. EPA agrees with the commenter's suggestion that this general condition should be clarified to state specifically that TMDLs must consider pollutant loadings resulting from wet weather events, where appropriate and where sufficient data are available. EPA believes TMDLs reflecting wet weather events would be appropriate where such events contribute the pollutant(s) during the flow conditions for which the TMDL is being developed. For example, the TMDL for a pollutant that has an annual averaging period (e.g., dioxin) would need to consider loadings from wet weather events because such events can occur during the yearly averaging period. However, a TMDL based on a 7-day critical low flow (e.g., lead) for a pollutant that has a 4-day averaging period would not

directly consider loadings from wet weather events because such events are unlikely to occur during critical 7-day low flows. Contributions from previous wet weather events would be considered through load allocations to the sediment. In addition, a TMDL based on dynamic or stochastic water quality model would include all dry and wet weather loadings from all sources. In any case, where the TMDL for the receiving water accounts for loadings that occur from wet weather events, the resulting WLAs, including those for POTWs, must be consistent with the TMDL and WLAs. The only exception to this is where the POTW discharge meets the definition of wet weather point source under 132.2. The final Guidance does not regulate wet weather point sources.

Many nonpoint sources and wet weather point sources as defined at section 132.2 of this Guidance typically have their greatest impacts following storm events and the influx of pollutants from these events needs to be factored in when establishing a TMDL to ensure attainment of water quality standards. Accordingly, EPA has inserted language to clarify this point in the final Guidance and has amended 132.4(e)(1) to provide specifically that procedure 3 applies to wet weather events, as appropriate. Like the proposal, the final Guidance does not require a specific procedure to address wet weather flows, but rather leaves it to the discretion of the State or Tribe to choose the most appropriate procedure, considering all relevant facility specific, pollutant specific, and receiving water specific factors.

In EPA's view, this clarification will not subject POTWs to any additional burden. Any adjustments to a POTW's permit conditions to account for wet-weather flows should be addressed through the NPDES permitting and enforcement policies and procedures. Finally, EPA disagrees with the comments asserting that wet weather contributions cannot be accurately estimated. A number of models currently exist to generate loadings estimates from a range of wet weather events. EPA is working on additional guidance on assessing pollutant loadings associated with CSOs and nonpoint sources (see "Technical Guidance for Estimating Total Maximum Daily Loads (TMDLs): Integrating Steady-State Episodic Point and Nonpoint Sources, draft, June 1994, available in the docket).

i. General Condition 9 - Background Concentrations of Pollutants

This general condition was numbered as general condition 8 in the proposal. As proposed, this condition established procedures for determining representative background concentrations of pollutants to assure that background concentrations are consistently considered in TMDL development among the Great Lakes States. The proposal included provisions for calculating background. The proposal defined background, described the choice of data set, the use of the geometric mean, and the treatment of data sets with data points above and below detection. EPA received no significant comments on the definition of background and the proposed language is retained in the final Guidance with only minor changes to account for the use of the term in procedure 5. The proposal, comments and the final Guidance for each provision are discussed below. EPA renumbered this provision as general condition 9 in the final Guidance to reflect the overall reorganization of procedure 3.B of appendix F.

i. Choice of Data Set

(A) Proposal: The proposal provided that the representative background concentration for a pollutant shall be established as the geometric mean of one of three possible data sets: available ambient water column data (e.g., ambient monitoring data), representative caged fish tissue data, or representative pollutant loading data. When more than one data set exists, best professional judgment (BPJ) would be used to determine which data set most accurately estimated background concentrations. The preamble to the proposal stated that, in general, ambient monitoring data are preferred over other sources of data. The preamble also recognized that there may be instances where other data sets may be more appropriate, such as where ambient data are not available, or where ambient data are not as informative or reliable as either caged fish tissue data or pollutant loading data because of limits in analytical detection methods.

(B) Comments: Several commenters supported EPA's proposal to allow States and Tribes to choose among data sources. Others suggested that, by allowing a choice of data sets, there was too much discretion allowed to the State or Tribe in establishing background levels and suggested that EPA provide more specific guidance on the choice of data sets.

One commenter suggested that States and Tribes should be required, where possible, to eliminate unrepresentative data from the data set using factual information and statistical methods. Commenters suggested that more recent data should take precedence over older data even when the more recent data set is smaller. Furthermore, they believe that data more than five years old should not be considered. One commenter suggested that fish tissue and pollutant loading calculations should be rejected as acceptable data sets when those calculations predict background concentrations above the criteria for ambient monitoring data and such concentrations were not detected by ambient monitoring.

Several commenters advocated that only ambient data be used to estimate background concentrations. Other commenters wanted the Guidance to require regulators to use ambient monitoring data to calculate background concentrations of pollutants when such data is available.

A number of commenters disagreed with the requirement to consider caged fish tissue data in calculating background concentration because procedures for the use of caged fish analysis have not been thoroughly evaluated, validated, or standardized. Several commenters believe that the quality data necessary to provide accurate background data using the caged fish approach is not available. Commenters suggested that using resident fish tissue as a basis for deriving background would be more accurate. A commenter further suggested that EPA attempt to calibrate the fish tissue and pollutant loading models with real data. Commenters also requested more specific procedural and technical information relating to use of caged fish data.

(C) Final Guidance: In response to comments and concerns, EPA has added resident fish tissue data as a fourth specified data set available for calculating background. Apart from that, EPA retains the proposed language with only minor modifications to ensure clarity and avoid redundancy.

In the final Guidance, EPA has consolidated into a single section the list of available data sets and the basis for determining what available data is acceptable for use in calculating background.

These provisions are now included in the subparagraph specifying calculation requirements. The final Guidance retains flexibility for States and Tribes to choose from among a number of data sets, including fish tissue data, in calculating background concentrations. EPA concludes that because of wide variability in the suitability of available data for a particular situation and because of site-specific considerations, use of BPJ is appropriate to make case-by-case determinations. EPA recognizes that more recent data, with improved detection or quantification levels may be more appropriate, while some older data with poorer detection or quantification levels may be less acceptable. However, EPA recognizes that, in some instances, the older data may be the only data available may be the only representative data of sufficient quality from which to make decisions and thus is not establishing a prohibition on the use of older data. In the final Guidance, the State or Tribe retains the flexibility to use BPJ to eliminate unrepresentative data or to give greater weight to the most recent data as suggested by commenters. States and Tribes may also use statistical techniques to identify and eliminate unrepresentative data.

The final Guidance thus does not include more specific direction to limit the use of any particular data set. Although EPA agrees with the commenters' suggestion that ambient monitoring data are generally preferred over other data sources, there may be situations where ambient data are not available, or are not as informative or reliable as either fish tissue or pollutant loading data because of limits in analytical detection methods. Because of limits in existing technologies, ambient data may still yield non-detects above criteria levels. Fish tissue data and pollutant loading data may be particularly useful alternatives for these situations.

EPA recognizes that caged fish tissue studies may have limitations in that such studies may not fully account for duration of exposure and food chain magnification. However, EPA has determined that such studies should be considered with other data sources in choosing among data sets to calculate background concentration. Aquatic organisms can serve as valuable indicators of whether water quality standards are being attained. The final Guidance also authorizes the use of resident fish tissue data, as suggested by commenters, because of concerns regarding food chain effects and in response to concerns about the lack of caged fish tissue data. Use of resident as well as caged fish tissue data is intended to provide more latitude in selecting the appropriate data set.

Like the proposal, the final Guidance does not provide a methodology to use in translating fish tissue concentrations to a water column concentration, or for evaluating their validity. EPA agrees that care should be exercised in determining what fish tissue data are representative of background pollutant concentrations and encourages permitting authorities to consult EPA guidance on this topic. For example, EPA recommends that when fish tissue data are available from resident fish the geometric mean is divided by the bioaccumulation factor pursuant to the methodology in appendix B of this final Guidance, to yield estimated ambient concentrations. See *Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual* (USEPA, September, 1989, EPA-503/8-89-002, available in the docket).

EPA believes that best professional judgment should be used to determine if caged fish tissue data is appropriate for calculating background concentration in a given situation. Furthermore, the use

of caged fish tissue data is not required unless no other data exist to calculate background pollutant concentrations. Even in a situation where only caged fish tissue data exists, a facility always has the option to collect alternative data that more accurately reflects background concentrations (e.g., ambient monitoring data). In addition, the final Guidance does not require that new fish tissue "studies" be conducted in the absence of existing fish tissue data.

ii. Geometric Mean

(A). Proposal: The proposal specified that the representative background concentration for a pollutant shall be established as the geometric mean of one of the selected data sets described in that paragraph and the preamble offered guidance for performing the calculations. EPA is retaining the proposed language in the final Guidance. The Agency received no significant comments on this provision.

As the preamble to the proposal explained, a geometric mean is calculated for the set of data chosen to represent background conditions. The geometric mean calculated is based on both measured concentrations and an appropriate methodology for treating measurements below quantification levels. For pollutant loading data, the geometric mean should be taken of pollutant loading data from individual sources. The individual means of each of the individual sources should then be added to estimate total loading to the receiving water. Background concentration is calculated by dividing total loadings by the volume of water available at the appropriate design flow. Design flow will vary depending on the criterion being implemented at the point immediately upstream of the watershed, water body or water body segment for which the TMDL, WLA in the absence of a TMDL, or preliminary WLA for the purpose of determining reasonable potential under procedure 5 of this Guidance is being established. For further discussion, see the preamble to the proposal at 58 FR 20929.

(B). Final Guidance: EPA received no significant comments on this provision. EPA believes that the use of the geometric mean is the best approach for calculating a median concentration from data chosen to represent background conditions. An arithmetic mean would be one appropriate method for calculating median values when a sample concentration is as likely to be above the true average concentration as it is to be below the true average concentration. However, concentration measurements in fish tissue and water are more likely to be below the true average concentration. Under these conditions, the geometric mean is an appropriate estimator for the median while the arithmetic average will generally produce a value that is higher than the median. More explicitly, fish tissue and water concentration measurements generally follow positively skewed probability distributions where the median is appropriately estimated by the geometric mean.

iii. Data Points Above and Below Detection

(A) Proposal: The proposal allowed the use of best professional judgment to determine which data points are acceptable. However, within a given data set, some data points may indicate that the pollutant was not present at levels capable of being detected by the analytical method used. For

these data points, the true concentration of the pollutant can be zero or is somewhere between zero and the detection level of the analytical method. Other data points may indicate that the pollutant was detected, but at levels below which the analytical method is capable of reliable quantification. For these data points, the true concentration will be between the detection level and the quantification level of the analytical method. Finally, there may be data points showing reliably quantified levels of the pollutant.

The proposed Guidance specified that the following assumptions be used in calculating background when, within a data set, some data points are determined to be above and others are below the detection level. The proposal included the following assumptions: data points reported at levels below detection shall be set equal to one half of the detection level; and data points reported at levels greater than the detection level but less than the quantification level, shall be set equal to the midpoint between the detection level and the quantification level. If all acceptable available data points in a data set are reported as below the detection level for a specific pollutant, then all the data for that data set are assumed to be zero.

Section 132.2 of the proposed Guidance included a definition of detection level that is identical in substance to the definition at 40 CFR 136.2(f). There is no similar long-established definition of the term quantification level. However, the proposal defined the quantification level as the concentration at which a particular substance can be quantitatively measured using a specified laboratory procedure. EPA solicited comment on the definition and on the issue of whether a particular degree of confidence should be specified.

(B) Comments: EPA received a number of comments on the proposal to assign values equal to one-half of the detection level to data points reported below the detection level when other data points in the data set were reported above the detection level.

Several commenters supported the use of one-half of the detection level as a default. Another commenter suggested that if 25% or more of the data points are quantifiable, the remaining values reported as less than the detection limit should be zero. One commenter advocated that the requirement to use one-half of the detection level as a background concentration be deleted and the evaluation left to best professional judgment. Another commenter recommended that if a large proportion of the data is reported as non-detect, assumptions regarding what value to assign should be left up to the permitting agency and that such determinations need to be made on a case-by-case basis rather than through the application of a general rule. Several commenters wanted EPA to allow the use of appropriate statistical methods for data sets that include a large number of values below the detection limit and further advocated that the final Guidance cite examples of such statistical methods. One commenter suggested that a statistically valid sliding scale be used to assign concentration values to any non-detect measurements. Another commenter expressed concern that the proposed approach will result in unrealistically high background concentrations for data sets with a large share of measurements below the detection level and suggested that the final Guidance include methods presented in "NCASI Technical Bulletin No. 621." Several commenters supported the use of one-half the detection level when calculating means or averages from data sets that include non-detect values.

EPA also received comments addressing situations where some of the data is between the

detection level and the quantification level. One commenter suggested that the final Guidance require the quantification level be used as the default value in determining the mean for pollutants that have caused or contributed to fish advisories downstream. Another commenter suggested that when data points are below the detection level or quantification level, zero or a default percentage of the criteria value, when the criteria value is also below the level of detection, should be assumed.

In situations where all the data points in a particular data set are below detection, several commenters agreed with the proposal that these data points should be assumed to be zero. One commenter suggested that for a data set of more than ten data points, the proposal should apply, but that if there are fewer than ten data points and all the data points are below detection, background shall be assumed to be one-half the detection level. Several commenters supported EPA's definition of quantification level. A few commenters did not support including the quantification level definition. Another commenter suggested that the definition of quantification level should be the same as that used in setting the Compliance Evaluation Level (CEL) for determining permit compliance in proposed procedure 8. The CEL was defined in the proposal, as the level at which compliance with an effluent limit is assessed. Some commenters advocated that the term "detection level" be changed to "method detection level" since the proposal defined detection level the same as method detection level is defined in 40 CFR 136.

(C) Final Guidance: The final Guidance recognizes the need for flexibility when calculating background using a data set containing data points both above and below the detection level or quantification level. EPA has concluded that, for these data sets, although default values of one-half of the reported detection level for data points reported as below detection, and the mid-point between the detection level and quantification level for data points reported below the quantification level and above the detection level, are a reasonable and appropriate estimate for purposes of calculating background concentration, they are not the only reasonable and appropriate approach. As many of the commenters pointed out, there are a number of commonly accepted statistical approaches to evaluating mixed data sets (also known as censored data sets). Therefore, in the final Guidance, States and Tribes are required to use commonly accepted statistical techniques to evaluate data sets containing values both above and below the detection level. Commonly accepted statistical techniques can include a variety of approaches, including the use of default values as proposed. Some commonly accepted statistical techniques are outlined in Chapter 14 of *Statistical Methods for Environmental Pollution Monitoring* (Richard O. Gilbert; published by Van Nostrand Reinhold) and *Truncated and Censored Samples* (A.Clifford Cohen; published by Marcel Dekker).

Because there is no universal method to reliably quantify pollutant concentrations below the detection level, EPA believes that using a default value of one-half of the reported detection level is a reasonable balance of a State and Tribes' obligation to provide dischargers with an appropriately stringent WLA and the statutory requirement that TMDLs ensure the attainment of water quality standards. The same reasoning applies when calculating WLAs in the absence of a TMDL. Likewise, EPA has concluded that the reasoning above also supports using the mid-point between the detection level and quantification level as an acceptable, reasonable approach for dealing with data points above the detection level but below the quantification level. In this situation, EPA does not endorse using the

detection level as a default value. Using the detection level as a default to calculate background could result in WLAs that would not provide the necessary assurances, as required by the CWA, that water quality standards will be attained. Again, EPA believes this is of particular concern for pollutants with criteria values below the level of detection.

EPA retains the approach in the proposal that assigns zero values to data points when all the data in the data set are below the level of detection for the particular pollutant. When all analytical tests for a chemical result in determinations that fall below the detection level, one would have, in effect, a finding that the target analyte cannot be known with confidence to be present in any of the samples. Where this is the case, and no other analytical results are available to indicate that the chemical may be present in any sample, EPA believes the appropriate finding is that the chemical is not present. In contrast, as described above, where analytical tests show the chemical to be present in some samples, EPA believes that an appropriate and reasonable approach is to assume that the chemical may be present even in those samples in which the chemical is not detected, and therefore assign a value to the non-detect measurement of one-half the value of the detection level. Although EPA recognizes that this could potentially result in an underestimate of background concentration for a given pollutant, it could also result in an overestimate of background concentration for a given pollutant. EPA believes that this approach is reasonable because it strikes a balance between the desire to accommodate dischargers with a reasonable WLA and the CWA requirement that TMDLs ensure the attainment of water quality standards. In addition, as discussed in the preamble to the proposal, there is no universal method to reliably quantify pollutant concentrations below the detection level. States and Tribes may want to consider a more stringent approach, whether as a general matter or in establishing individual TMDLs, as authorized by section 510 of the Clean Water Act and general condition 6 of this procedure.

EPA is retaining the proposed definition of "quantification level" for purposes of this procedure. EPA has concluded that a standard definition of quantification will improve consistency among States and Tribes in the Great Lakes System when calculating the background concentration of pollutants. Consistency among Great Lakes States and Tribes is one of the major objectives of the final Guidance, although the definition is broad enough to allow consideration of other factors as appropriate. For example, a State or Tribe may consider the nature of the pollutant, the method being used, and the past performance of the testing facility or laboratory. In addition, EPA agrees with commenters that asserted the proposed definition of "detection level" is confusing since it is substantively identical to the existing 40 CFR 136 definition of "method detection level." EPA has therefore, renamed "detection level" to "method detection level" to avoid confusion and maintain consistency. Substantively, the text of the definition was not changed.

A State or Tribe's use of procedures for estimating representative background concentrations of pollutants will also be reviewed by EPA on a case-by-case basis when it approves or disapproves State or Tribal TMDLs submitted under section 303(d). A State or Tribes's approach will be reviewed as part of the program submission and adoption process set forth at section 132.5 of this Guidance. EPA also retains the authority to object to an NPDES permit containing a WQBEL derived from a WLA in the absence of a TMDL if EPA determines that the estimates of representative background concentrations were unreasonable and that the permit would therefore not implement water quality

standards as required by section 301(b)(1)(C) of the CWA.

The only substantive change to the proposal is the addition of language authorizing the use of commonly accepted statistical techniques in evaluating data sets consisting of values both above and below the method detection level. EPA added this additional flexibility in response to a number of comments supporting the use of such approaches. EPA encourages the use of commonly accepted techniques. Such statistical approaches can be a useful tool when dealing with sparse data sets. In all other respects, general condition 9 is substantively the same as the proposal, except that it states explicitly that it applies to data sets having values both above and below the method detection level. The final Guidance has also been modified to ensure that the term "reported" is used consistently throughout this condition.

j. General Condition 10 - Effluent Flow

General condition 10 in the proposal provided that, if WLAs are expressed as a concentration of a pollutant in a discharge, the TMDL must also specify the point source effluent flow assumed in deriving the WLA. Since TMDLs are based on mass loadings to a system, the assumed flows used to derive the mass loadings need to be specified. This provision also facilitates the establishment of mass loading limitations in NPDES permits as required by procedure 7 of appendix F. Substantive comments on establishing an effluent flow are addressed in the loading limits section of this document (section VIII.G). The final Guidance retains the proposed language with minor changes to improve clarity. This should assure that common assumptions are used in establishing TMDLs and corresponding NPDES permit limits.

k. General Condition 11 - Reserved Allocations

i. Proposal: General condition 11, as proposed, provided that once a TMDL for a particular pollutant is in place for a waterbody, a new source or new discharger can discharge that pollutant to the waterbody only if its loadings are consistent with the existing TMDL. The existing TMDL must include a reserved allocation for future growth or the TMDL must be revised to include an allocation for the new discharge.

ii. Comments: Many commenters suggested that the provision related to the use of "reserved allocations" for future growth should be strengthened to require that a specific share be set aside. One commenter suggested that EPA should describe the procedure to determine a reasonable reserve capacity for future growth while allowing the State the discretion to make this determination.

iii. Final Guidance: The final Guidance makes only minor modifications to change the title from "New Source or Discharger" to "Reserved Allocations" and to clarify that the general condition applies only to new discharges of the particular pollutant for which the TMDL was developed. The purpose of general condition 11 is to assure that the impacts of new pollutant sources will be considered. Without such a condition, a TMDL might fail to take into account new discharges of the pollutant of concern with the result that the TMDL would need to be revised in order to allow the new

discharge. While EPA appreciates the comments urging that this provision be strengthened by establishing a specific procedure for reserving capacity for future growth, EPA believes that States and Tribes are in the best position to determine a reasonable allocation for future growth and thus the final Guidance provides them the flexibility to make the determination. States and Tribes will need to make the determination by balancing local and economic development with water quality requirements.

4. Special Provisions for BCCs

a. Proposal: The proposed Guidance recommended restrictions on the introduction of bioaccumulative chemicals of concern (BCCs) in the Great Lakes System by specifying, in general, that mixing zones for existing dischargers of BCCs be eliminated within 10 years of the effective date of this final Guidance, and for new dischargers or new sources, that no mixing zone for BCCs be provided. The proposal also specified that mixing zones calculated during the ten year phase-out period prior to elimination of mixing zones for BCCs would be established using the mixing zone provisions for non-BCCs, set forth in sections C and D of proposed options A and B. The proposal allowed a limited exception to the elimination of mixing zones for BCCs when water conservation measures result in an increased concentration but lead to an overall reduction in load.

b. Comments: EPA received numerous comments both supporting and opposing the provision to eliminate mixing zones for BCCs. Many commenters supported the phase-out of mixing zones for all discharges of BCCs within the Great Lakes System. Several of these comments pointed out that the proposed elimination of mixing zones is consistent with the Great Lakes Water Quality Agreement's emphasis on limiting any future introduction of persistent toxics into the Great Lakes System.

A number of commenters urged that the elimination of mixing zones be broadened to include all persistent toxic chemicals, not just BCCs. Several commenters specifically mentioned the need to address lead and cadmium. One commenter suggested that in order to ban the discharge of toxic substances into the Great Lakes Ecosystem, EPA needs to ensure that all sources of pollution, including air, contaminated sediments and runoff, are controlled and that EPA should require comprehensive pollution prevention programs throughout the basin. One commenter suggested that while mixing zones for BCCs should, in general, be eliminated, mixing zones should be allowed under strict conditions, such as when pollution prevention measures are implemented and have resulted in reduced loadings.

Many commenters opposed the elimination of mixing zones for existing dischargers of BCCs and believe that the mixing zone prohibition is unattainable and inefficient. Many commenters mentioned that there would be high costs associated with elimination of mixing zones in return for limited environmental benefits. Commenters claimed that the elimination of mixing zones requiring dischargers to meet criteria end of pipe would, in effect, result in a zero discharge requirement.

Several municipalities mentioned that they would be unable to impose additional requirements on their industrial dischargers that would allow them to meet water quality goals without mixing zones. They also felt the phase-out of mixing zones for BCCs would provide a disincentive for them to take on

new industrial dischargers.

Many commenters suggested that if mixing zones are phased out, reductions must be limited to levels that are economically and technically feasible. Several commenters advocated that additional pollution prevention measures also be required to help minimize the release of BCCs into the Great Lakes.

Commenters also suggested that eliminating mixing zones for BCCs may not be the most cost-effective means of reducing certain BCC loadings (e.g., mercury) and that reductions need to come from other sources, such as atmospheric deposition. Commenters suggested that greater load reductions would occur if nonpoint sources were targeted for controls. Commenters asserted that extraordinary controls on point sources of BCCs will have little impact on water quality because point sources only contribute a small percentage of the total load of BCCs to the basin and that the major loading of BCCs is from nonpoint sources. Several commenters claimed that the increased stringency in permits would not lead to an overall improvement in ambient water quality and that limits without mixing zones would be unduly restrictive.

Numerous commenters stated that the elimination of mixing zones has no scientific merit and is merely a policy decision. Many commenters pointed out that existing EPA technical guidance, such as the Technical Support Document for Water Quality-based Toxics Control (TSD), does not disallow mixing zones. Commenters suggested that existing EPA and State policy should determine when mixing zones are appropriate. One commenter advocated that methods recommended in the TSD be used to predict the fate and transport of pollutants such as BCCs and that these approaches be used to develop TMDLs for the BCCs rather than disallowing mixing zones.

A number of commenters indicated that the proposed time frame for the phase-out is reasonable. One commenter suggested that the final Guidance should make it clear that the mixing zone phase-out for existing discharges will be effective ten years after the Guidance is incorporated into state rules rather than ten years after publication of the final Guidance. Numerous environmental groups suggested that the implementation period is too long and recommended an accelerated phase-out of mixing zones for BCCs. Many supported a 5-year phase-out rather than 10 years. Commenters specifically suggested partial reductions of mixing zones, in terms of the available dilution ratio, be used at the time of the first NPDES permit reissued after the final Guidance is published.

One commenter advocated that EPA establish a mass loading-based limit on the proposed water conservation exemption by placing a cap on the increased concentration allowed in exchange for water conservation measures. Commenters supported the proposed restriction that the mixing zone granted under this provision be consistent with the mixing zone provisions of sections C (deriving TMDLs for discharges to Lakes) and D (deriving TMDLs for discharges to Tributaries) of proposed procedure 3.

c. Final Guidance: The final Guidance retains the ten-year phase-out of mixing zones for BCCs and the immediate elimination of mixing zones for new discharges, which are defined for the

purpose of procedure 3.C as (i) discharges from new Great Lakes dischargers; or (ii) a new or expanded discharge from an existing Great Lakes discharger. All other discharges of BCCs are defined as existing discharges. The final Guidance is consistent with the Steering Committee's policy that every reasonable effort be made to reduce all loadings of BCCs to the Great Lakes System. The Steering Committee recommended that mixing zones be eliminated for BCCs as a way to reduce mass loadings to the Great Lakes. However, in response to numerous comments that the proposed phase-out may be technically or economically infeasible, the Guidance does provide a limited exception to the elimination of mixing zones for existing discharges of BCCs to the Great Lakes System. This exception is provided only in limited circumstances when the State or Tribe finds that the discharger seeking the exception is implementing controls to reduce the BCCs for which a mixing zone is sought to the maximum extent possible yet still cannot meet a WQBEL based on no mixing zone. EPA has concluded, after considering all the comments, that elimination of mixing zones for BCCs may not be reasonable in all circumstances, and thus has provided for a limited exception (described below) in the final Guidance.

The final Guidance uses the terms "new Great Lakes discharger" and "existing" Great Lakes discharger as discussed in section II.B of this document. In the final Guidance, the time deadline has been clarified to provide that mixing zones for existing Great Lakes dischargers will be phased-out within twelve years from the date of publication of the final Guidance. The proposal set the phase-out at ten years, but this has been modified in the final Guidance to reflect explicitly the two years allowed for State and Tribal adoption of implementation procedures for the final Guidance. The phase-out deadline for new Great Lakes dischargers is stated in the final Guidance as two years after publication of the final Guidance.

The phase-out of the elimination of mixing is consistent with existing EPA regulations and guidance, and the Great Lakes Water Quality Agreement. EPA regulations provide that States and Tribes may, at their discretion, provide for mixing zones as part of their State and Tribal water quality standards (40 CFR 131.13). However, the Technical Support Document for Water Quality-based Toxics Control recommends that States and Tribes provide a definitive statement in their water quality standards as to whether or not mixing zones are allowed and suggests that: "As our understanding of pollutant impacts on ecological systems evolves, there may be cases identified where no mixing zone is appropriate." For example, EPA's Water Quality Standards Handbook (EPA-823-B-93-002) states that "Careful consideration must be given to the appropriateness of a mixing zone where a substance discharged is bioaccumulative, persistent, carcinogenic, mutagenic, or teratogenic." The Handbook recommends that "denial (of mixing zones) should be considered when bioaccumulative pollutants are in the discharge."

A general principle of the Great Lakes Water Quality Agreement (see Annex 2 Paragraph 2.(d)) supports the elimination of point source impact zones (i.e., mixing zones) for toxic substances as consistent with the overall policy of the virtual elimination of persistent toxic substances. According to the Agreement, pending the achievement of the virtual elimination of persistent toxic substances, the size of such zones shall be reduced to the maximum extent possible by the best available technology so as to limit the effects of toxic substances in the vicinity of these discharges.

Although levels of certain bioaccumulative chemicals of concern (BCCs) have significantly declined in the Great Lakes System in recent years, EPA estimates that under current loadings it will take years, perhaps decades, for fish tissue concentrations of certain BCCs to decline to levels that would allow unrestricted consumption of fish in the Great Lakes. Due to the unique characteristics of the Great Lakes, special limitations are necessary to reduce loadings of BCCs to assure that similar problems do not occur in the future for other BCCs. For a more thorough discussion of ambient concentrations of BCCs, see sections I and II.C.8 of this document.

A number of commenters mentioned that there would be significant costs associated with complying with the mixing zone ban for existing discharges and that EPA should not mandate reductions that are technically and economically infeasible. Mixing zones allow facilities to exceed applicable water quality criteria in a portion of the stream segment or lake close to the discharge point. EPA recognizes that, in certain limited situations, the elimination of mixing zones for BCCs for existing discharges may be technically or economically infeasible, and in limited circumstances, may not be a reasonable approach despite the ten-year phase-out period. Therefore, the final Guidance provides a process whereby a State or Tribe may grant a mixing zone for existing discharges of BCCs in limited circumstances. EPA emphasizes that no such exception to the mixing zone prohibition is authorized for new Great Lakes dischargers or new or expanded discharges from an existing Great Lakes discharger because EPA has determined that facilities contemplating such discharges have more flexibility in designing and constructing their processes and treatment technologies to meet applicable water quality criteria at the point of discharge. In addition, EPA notes that States and Tribes are not required to grant mixing zones in any instance.

The final Guidance authorizes the granting of a mixing zone for BCCs for existing discharges, after the phase-out period, only upon finding that: (1) the facility is in compliance with and will continue to implement all applicable treatment and pretreatment requirements of Clean Water Act sections 301, 302, 304, 306, 307, 401, and 402, including existing NPDES water-quality based effluent limitations; and (2) the discharger has reduced its discharge of the BCC for which a mixing zone is requested, and will continue to implement controls to further reduce such discharge, to the maximum extent possible. Because of concerns about the impacts of BCCs to the Great Lakes System and the significant public support for the elimination of mixing zones for BCCs, EPA intends that this exception only be granted in limited situations.

In making a finding that a discharger has reduced the discharge of BCCs for which the mixing zone is sought to the maximum extent possible, the State or Tribe should consider the availability and feasibility of additional controls for that discharger to reduce and ultimately eliminate BCCs, including those controls and strategies used by similar dischargers. For purposes of this subparagraph, "similar dischargers" is to be interpreted broadly to include, at a minimum, facilities with similar industrial or treatment processes, similar pollutants, and similar products or similar by-products.

For purposes of determining whether to grant a mixing zone for an existing discharges of BCCs after the phase-out period, the State or Tribe should also consider whether the discharger, or affected community or communities, will suffer severe economic hardship if the mixing zone is eliminated. In

evaluating economic impacts, State or Tribe should consider costs of all pollution reduction options including available treatment technologies and control strategies beyond those already being implemented. Costs should reflect design and current operating flow. States or Tribes should also evaluate the influent water quality, type of BCC, volume of effluent and concentration of the BCCs for which the mixing zone is being sought present in the effluent, and ambient receiving water quality. Finally, the State or Tribe should evaluate information on the facility's current financial health including, where appropriate, existing municipal and pretreatment user charges and existing profitability. Where appropriate, the State or Tribe may also want to consider information on the current profitability and overall financial health of the facility's parent corporation, where such information is available. EPA expects that factors to be considered in assessing economic impacts will vary on a facility-by-facility basis. (See Economic Guidance for Water Quality Standards - Workbook, Draft, November 1993, available in the docket for this rulemaking.) The State or Tribe should also evaluate potential effects on employment rates, tax revenues, and where appropriate, on user fees from increased costs associated with meeting water quality criteria in the absence of a mixing zone.

Under the final guidance, a mixing zone for a BCC may be granted only if the permitting authority determines, inter alia, that the discharger has reduced its loadings of that BCC to maximum extent possible. Therefore, an exception to the mixing zone elimination provision may not be granted if pollution prevention and/or control and treatment strategies exist that make it technically possible for the discharger to achieve the applicable water quality criteria at the point of discharge, and if the discharger, or affected community or communities, will not suffer severe economic hardship in implementing such strategies. For example, in assessing whether the discharger has reduced its discharge of the BCC for which a mixing zone is requested to the maximum extent possible, the State or Tribe should consider the availability and feasibility of alternate treatment technologies and control strategies including pollution prevention measures that reduce and eliminate BCCs, and whether or not these technologies and strategies are currently being implemented by the facility. Relevant strategies include those that would apply both to the facility and upstream sources (e.g., a municipalities's industrial users). After evaluating alternate technologies and strategies, the permitting authority should consider the technical reasons that implementation of some or all of them cannot reasonably be expected to eliminate the discharger's need for a mixing zone. EPA emphasizes that this exception to the elimination of mixing zones for existing discharges of BCCs is intended to be very limited and only granted in exceptional circumstances. In addition, if a mixing zone for existing discharges of BCCs is proven necessary, the State or Tribe should only grant the amount of mixing needed to address the remaining technical and economic limitations. In no circumstance should the amount of mixing allowed exceed the maximum mixing zones specified for non-BCCs in sections D (deriving TMDLS for discharges to Lakes) and E (deriving TMDLS for discharges to tributaries) in procedure 3 of appendix F.

The State or Tribe should also consider whether or not the discharger agrees to develop and implement an ambient monitoring plan. Monitoring data compiled by dischargers could be used to supplement State or Tribal monitoring data and provide additional information on receiving water assimilative capacity and on the extent of impacts, if any, associated with the mixing zones. Ambient monitoring data would be used, in attained waters, to ensure compliance with water quality criteria at the edge of any mixing zone, and in non-attained waters to ensure that the projected improvement in

water quality under the TMDL or comparable assessment and remediation plan is occurring. Ambient monitoring data can also be used to provide the basis for future decisions on the granting of mixing zones for BCCs. The State or Tribe is encouraged to seek additional information, as necessary, to determine whether a mixing zone for BCCs is warranted for an existing discharge.

The final Guidance incorporates a number of limitations on any mixing zones for existing discharges of BCCs granted after March 23, 2007. Specifically, under the final Guidance, no mixing zone for existing discharges of BCCs shall result in any less stringent limitations than those existing prior to March 23, 1997. Furthermore, the mixing zone shall be limited to one permit term. Mixing zones may not be granted thereafter unless the State or Tribe makes the necessary findings discussed above for each successive permit application in which a mixing zone for BCCs is sought. The size of the mixing zone shall also be evaluated and shall reflect all new information obtained by the State or Tribe in considering mixing zones for BCCs after the phase-out. In addition, any mixing zone for BCCs granted under this exception for attained waters must protect all designated and existing uses of the receiving water and must ensure the attainment of applicable aquatic life, wildlife, and human health criteria. In non-attained waters any mixing zone granted for BCCs under the exception must be consistent with the TMDL or comparable assessment and remediation plan under procedure 3.A of appendix F.

EPA recognizes that pollution prevention approaches are an effective means of reducing loadings to the environment and are usually less costly than treatment. Thus, the final Guidance provides that, in granting any exception to the mixing zone elimination provision for existing discharges of BCCs, the State or Tribes needs to ensure that the discharger has developed and conducted a pollutant minimization program for that pollutant consistent with procedure 8 of the Guidance, where applicable. Procedure 8 of the final Guidance provides that when a water quality-based effluent limitation for a pollutant is determined to be less than the quantification level, the permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program. The goal of the pollutant minimization program is to reduce all potential sources of the pollutant and thus to maintain the effluent at or below the WQBEL. Based on current detection levels for the twenty-eight BCCs that are included in Table 6 of the final Guidance as pollutants of Initial Focus in the Great Lakes Water Quality Initiative, it is estimated that 22 of the BCCs will have criteria established at levels below what the most sensitive analytical techniques can currently quantify, and will also likely result in WQBELs less than their quantification levels. Therefore, EPA believes that in most instances, a facility will already be required to develop pollutant minimization programs for most BCCs. It is possible that in some situations, addition of a mixing zone may result in an increased limit that will then cause the WQBEL to be greater than the quantification level; procedure 8 would no longer apply and a pollutant minimization program would no longer be required. In those instances, States and Tribes should consider requiring the permittee to develop and conduct a pollutant minimization program as a condition of receiving the mixing zone for BCCs.

Finally, the final Guidance provides that no mixing zone for a BCC shall be granted unless alternative means for reducing BCCs elsewhere in the watershed are evaluated. This limitation reflects concerns raised by many commenters that nonpoint source contributions of BCCs might be more significant than point source contributions and therefore nonpoint sources should be taken into account

when determining the availability of mixing zones for existing point source discharges of BCCs. This evaluation can be conducted either by the State or Tribe or by the discharger seeking the mixing zone for BCCs. EPA expects that this evaluation may identify opportunities to reduce BCC loadings within the watershed from other sources and may facilitate a more effective and less costly strategy for point sources to achieve overall reductions in BCCs. EPA expects controls necessary to obtain additional reductions in BCCs will be implemented under existing State, Tribal, federal and local authorities and believes that this provision will provide additional incentives for dischargers to assist States and Tribes in identifying other sources of BCCs. As suggested by some commenters, reductions of some of these nonpoint source loadings may prove to be more cost-effective and may result in greater environmental benefits than would be achieved by increasing controls on point sources.

The final Guidance provides that exceptions to the mixing zone elimination provision will be granted solely at the discretion of the State or Tribe on a case-by-case basis. States or Tribes may also choose not to authorize such exceptions as part of their part 132 adoption, and thus could simply require the elimination of mixing zones for existing discharges of BCCs no later than March 23, 2007.

Because of the importance of controlling BCCs in the Great Lakes System, it is critical that the public have an opportunity to comment on permit-specific exceptions to the general policy of eliminating mixing zones for existing dischargers of BCCs. The final Guidance provides that each draft permit that includes a mixing zone for one or more BCCs after the phase-out period must specify, either in the fact sheet or in the statement of basis for the draft permit, the mixing provisions used in calculating the permit limits, and must identify each BCC for which a mixing zone is proposed. The draft permit, including the fact sheet or statement of basis, is required to be publicly noticed and made available for public comment under 40 CFR 124.6(e). The final Guidance also specifies that any mixing zone for existing BCC dischargers authorized under procedure 3.C.6 of appendix F must also be consistent with procedure 3.D and 3.E of appendix F.

Under the final Guidance, the elimination of mixing zones will continue to be limited to BCCs. BCCs are the pollutants of primary concern in the Great Lakes System. Documented widespread impacts warrant the special emphasis on controlling BCCs (see section I of this document, and the preamble to the proposal at 58 FR 20806). In addition, States already have the discretion under current EPA regulations to eliminate mixing zones for other persistent chemicals such as lead and cadmium.

The final Guidance retains the ten year phase-out period for existing discharges but clarifies that this begins after States and Tribes adopt the part 132 implementation procedures. As authorized by section 132.5, States may be granted up to two years in which to adopt and submit for EPA approval criteria, methodologies and policies and procedures consistent with the final Guidance. The ten year time period corresponds to two five-year NPDES permit terms. EPA has determined that it represents a reasonable period for implementing the mixing zone phase-out and that this period is consistent with the Great Lakes Water Quality Agreement goal of virtual elimination of persistent toxic substances.

EPA has concluded that a shorter time period for existing Great Lakes discharges, such as a

phase-out within five years as suggested by some commenters, may not afford facilities with existing discharges sufficient time to retrofit existing treatment technologies or to adopt new pollution prevention or alternative control strategies as necessary to achieve the applicable water quality criteria at the point of discharge. Therefore, EPA is retaining the proposed ten year phase-out period. EPA notes, however, that States and Tribes may choose to establish a shorter phase-out time when they adopt the final Guidance.

The proposal also included a provision that WLAs be set at a more stringent level than the most stringent water quality criteria or values if necessary due to background concentrations to meet criteria and values at the point of discharge. This clause has been omitted from the final Guidance. The final Guidance provides simply that the WLA for new and existing discharges of BCCs shall be set equal to the most stringent applicable water quality criteria or values for the BCC in question. This would also be the case for a BCC for which the water body is in non-attainment. See section VIII.E.2.h of this document for a discussion of the rationale. Section 301(b)(1)(C) and 402 of the Clean Water Act and implementing regulations address discharges to non-attained waters and ensure that limitations more stringent than criteria will be imposed where appropriate; thus EPA determined that the omitted clause was unnecessary.

EPA has made other modifications to the mixing zone section. The order of this section has been rearranged to correspond to the chronological sequence of events. Also, the final Guidance clarifies that specific provisions in this section apply to WLAs calculated in the absence of TMDLs and preliminary WLAs developed for purposes of determining reasonable potential under procedure 5 of appendix F, as well as to the development of TMDLs. This change reflects the modification to General Condition 1, discussed above, which no longer specifies that TMDLs must be developed prior to the issuance of a new or revised NPDES permit upon a finding of reasonable potential. WLAs and corresponding WQBELs may be calculated in the absence of a TMDL. The new reference in this section is intended to clarify that these mixing zone provisions apply even in those situations when no TMDL has been established.

The final Guidance retains the exception to the mixing zone elimination for BCCs for existing discharges from a facility implementing water conservation measures. EPA recognizes that, as a result of water conservation measures, concentrations of a BCC in an effluent may increase, while the mass of the BCC being discharged does not. EPA concludes that because water conservation is desirable, an exception may be appropriate in certain circumstances. The primary concern for BCCs is the mass of the pollutant entering the Great Lakes System. EPA agrees with commenter's concerns regarding allowable increases above criteria and has retained the provision that restricts mixing zones under the water conservation provision to those allowed for non-BCCs (i.e., a 10:1 dilution ratio for lakes and 25 percent of design flow for tributaries).

5. TMDLs for Open Waters of the Great Lakes (OWGLs)

Both options A and B described the process for developing TMDLs for open waters of the Great Lakes (OWGLs), inland lakes and other waters of the Great Lakes System that exhibit lentic

conditions {see proposed sections 3A.C (58 FR 21036) and 3B.C (58 FR 21039)}. Both options provided general guidance for development of TMDLs on a lake-wide basis, including specifications for mixing zones for non-BCCs, calculation of load allocations, protection from acute effects, procedures when high background concentrations are present, and a provision for a margin of safety for chronic and acute effects.

In the final Guidance, language has been added to state explicitly that TMDLs developed under this section must comply with General Conditions 1 through 11 and requirements of section 303(d) of the CWA and 40 CFR 130.7. (see citations under general condition 1 in procedure 3 of appendix F). The final Guidance also identifies the provisions of this section that apply for purposes of calculating WLAs in the absence of TMDLs and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of appendix F. Aspects of both procedures 3A and 3B have been retained in the final Guidance and modifications to specific components of the proposal are described in more detail in the following sections. It should be noted that nothing in this section should be construed as authorizing mixing zones for BCCs that are prohibited under procedure 3.C of appendix F. These procedures are to be used, however, when establishing a mixing zone allowed under procedure 3.C of appendix F.

a. Mixing Zones for non-BCCs

i. Proposal: Both options provided that, absent a mixing zone study, individual wasteload allocations for point sources shall not be based on a mixing zone larger than is provided by mixing one part effluent with ten parts lake water, including background concentrations of pollutants. Option A described the 10:1 mixing zone in a narrative format, while Option B embodied the concept in a formula. Option B included language providing that in no case shall the permitting authority grant a mixing zone that exceeds the area where discharge-induced mixing, i.e., the area in which the momentum from the discharge pipe ceases to have a major impact, occurs.

Under proposed Option B, for non-BCCs, when a facility believes the actual area of discharge-induced mixing is greater than 10:1, a larger mixing zone could be allowed if a mixing zone demonstration is successfully completed in accordance with proposed section 3B.E. Under Option A, the mixing zone available is not necessarily constrained by the area of discharge-induced mixing if a facility demonstrates that an alternative mixing zone is appropriate for protection of designated and existing uses and implementation of all criteria and values.

ii. Comments: Several commenters disagreed with the provision limiting allowable mixing zones to the area of discharge-induced mixing. Several commenters advocated that credit be given for the use of diffusers and other forms of enhanced mixing to increase discharge-induced dilution.

Several commenters suggested that there is not sufficient justification for a maximum dilution factor and therefore disagreed with the 10:1 specified in the proposal. One commenter stated that the studies cited in the proposal support setting the 10:1 factor as a default value but do not provide a scientific basis to establish the 10:1 as a maximum. Several commenters mentioned that the proposal is

inconsistent with existing State mixing zone policies and recommended that the final Guidance be modified to allow each State to use its existing mixing zone provisions, which have already been approved by EPA.

One commenter advocated that mixing zones be prohibited for new source discharges of non-BCCs to lakes unless a mixing zone demonstration was conducted by a discharger. One commenter suggested that, for new sources, a dilution factor of up to 75% should be allowed without a mixing zone demonstration.

iii. Final Guidance: The final Guidance consolidates aspects of both options A and B into one provision. Like both options, the final Guidance specifies that WLAs calculated in the absence of a TMDL and preliminary WLAs for purpose of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution rate than one part effluent to 10 parts receiving water. The final Guidance clarifies that this dilution factor applies to both new and existing dischargers. Language appearing in both proposed options was modified to clarify that the provision applies to WLAs developed both for numeric and narrative criteria. The final Guidance retains the provision in Option B that limits the area of the mixing zone to the area of discharge-induced mixing. Consistent with both proposed options, a larger mixing zone is allowed if a facility successfully completes a mixing zone demonstration pursuant to procedure 3.F of appendix F. As discussed below, the final Guidance adopts the mixing zone demonstration provisions proposed as part of Option B.

As described in the preamble to the proposal (58 FR 20932), the 10:1 mixing factor was derived from mixing zone studies conducted for the Milwaukee Metropolitan South Shore wastewater treatment plant and for the Green Bay Metropolitan wastewater treatment plant. For these cases, it was shown that the 10:1 mixing factor represented an area of mixing where the velocity and momentum associated with an effluent being discharged from the end of a pipe was dissipated and any further dilution or mixing that then occurred was associated only with the typically slower natural process of diffusion, wind, temperature or current induced dispersion. While recognizing that mixing zone allocations are largely a policy decision, EPA believes that these studies provide a scientific basis for default mixing zone assumptions for discharges to open waters of the Great Lakes. The final Guidance does allow for recognition of site-specific conditions by allowing alternative mixing zones subject to the mixing zone demonstration requirements set forth in procedure 3.F of appendix F. EPA recognizes that mixing zone demonstrations are subject to resource and timing constraints.

EPA acknowledges that different situations, such as the use of diffusers and other technologies to enhance mixing, may increase the area of discharge-induced mixing, thereby warranting a larger dilution factor; and the final Guidance authorizes States and Tribes to afford dischargers the opportunity to demonstrate that an alternative mixing zone is appropriate. However, in the interest of ensuring consistency throughout the Great Lakes System, in the absence of site-specific data from a mixing zone demonstration, EPA has determined that a maximum default mixing factor of 10:1 will be retained in the final Guidance.

b. Calculating Load Allocations

Under both proposed Options A and B, State law formed the basis for determining appropriate dilution assumptions to be used on a case-by-case basis when establishing load allocations for nonpoint sources for OWGLs, inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. This is consistent with the general approach in the Guidance which generally allows States and Tribes flexibility to use their own procedures to address nonpoint source contributions to these water bodies.

EPA received general comments regarding the need to give States and Tribes flexibility to consider site-specific factors in addressing point and nonpoint source pollutants in developing TMDLs. The final Guidance retains the proposed language allowing States and Tribes the flexibility to consider appropriate mixing zone assumptions for nonpoint sources, consistent with applicable State and Tribal requirements.

c. Protection from Acute Effects

i. Proposal: Both options included provisions to assure attainment of acute criteria and values within the allowable acute mixing zones for discharges to the OWGLs and other waters described in paragraph B. Option A did not include a specific cap, but instead relied on site-specific analyses of limits necessary to assure attainment of acute criteria and values within the applicable acute mixing zone. Option B specified that effluent limitations for point sources may not exceed a final acute value (FAV). The preamble to the proposal noted that, in some circumstances, however, an effluent limit based on an acute mixing zone may need to be more stringent than the FAV to protect against acute effects within the mixing zone. The FAV is defined as twice the Criterion Maximum Concentration (CMC) (see section 132.2) of this final Guidance. Therefore, if the effluent is at twice the maximum concentration for protection against acute effects, acute toxicity may occur near the point of discharge depending on site-specific conditions.

ii. Comments: Most commenters opposed the use of acute mixing zones. Several advocated eliminating mixing factors altogether, at least in sensitive and/or impaired areas. Several commenters suggested that acute mixing zones for non-BCCs be developed on a case-by-case basis without an automatic FAV limit (Option A). Other commenters recommended the use of best professional judgment instead of a specified cap.

A number of commenters preferred the Option A acute mixing zone provisions to Option B because they suggested that the mixing zone limit in Option B is inconsistent with existing State policies. Other commenters argued that Option B sets an arbitrary constraint on mixing zones.

Several commenters preferred Option B because it is numeric and thus provides a well-defined benchmark for more consistent application in the Great Lakes System. Commenters argued that Option B should be mandatory, not discretionary. Several commenters were concerned that mixing zones under Option A could be substantially larger than under Option B and would not promote consistency in permit limits among States and Tribes. Many commenters were concerned that Option A provides too much discretion for establishing mixing zones and dilution flows, and that Option B,

which delineates a calculation method, is needed to promote uniformity across the Great Lakes System.

Several commenters expressed confusion because the proposed Guidance specifically listed Criterion Maximum Concentration (CMC) values, thereby implying that such values should be used in establishing permit limits, while the TMDL implementation procedure allowed permit limits up to the FAV (twice the CMC value).

iii. Final Guidance: The final Guidance provides that WLAs based on acute aquatic life criteria or values for discharges to the OWGLs and other waters described in paragraph B must not exceed the Final Acute Value (FAV). As proposed in Option A, the final Guidance also requires that a WLA based on such criteria and values be reviewed to assure that it prevents acute effects at the boundary of any acute mixing zone allowed under State law.

In the final Guidance, EPA combines the two proposed approaches into a single provision. EPA acknowledges the concerns raised by commenters regarding acute mixing zones and has retained language from Option B specifying a cap based on the FAV for acute mixing zones in order to promote consistency in developing permit limits within the Great Lakes System, while also minimizing areas of acute toxicity. EPA agrees with commenters that a numeric benchmark should ensure consistency better than narrative considerations. In response to comments, the final Guidance also provides that if mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to assure that criteria and values will be met in the area where any applicable acute mixing zones overlap. In addition, EPA agrees with commenters that site-specific considerations might authorize a larger mixing zone than otherwise authorized by the FAV cap. Accordingly, the final Guidance allows the use of a mixing zone demonstration to exceed the FAV if the demonstration is conducted and approved pursuant to procedure 3.F of appendix F.

EPA recognizes that some commenters, including some States, support eliminating acute mixing zones but notes that States and Tribes retain the authority to adopt provisions more stringent than those in the final Guidance consistent with CWA section 510. Accordingly, States and Tribes may eliminate mixing zones altogether or in selected locations such as sensitive and/or impaired areas. EPA is retaining the FAV cap for acute effects because it more accurately reflects discharge specific scenarios such as cases where there is rapid mixing (e.g., where high rate diffusers are used).

6. TMDLs for Discharges to Tributaries

The principal differences between options A and B in the proposal related to TMDL development for tributaries. The initial focus of Option A was on attainment of water quality standards throughout a basin, followed up with site-specific cross checks at discharge points throughout the basin. The site-specific cross checks would assure that standards are being attained around individual discharge points. Option A did not specify the size of mixing zones. Rather, it left such considerations to existing State requirements. Option B focused initially on evaluating limits needed for individual point sources, with supplemental emphasis on basin-wide considerations as necessary. Option B also included more detailed procedures including specific mixing zone requirements.

As discussed earlier in this document, EPA has decided that one procedure will apply for development of TMDLs for tributaries to the Great Lakes in order to ensure that some level of consistency applies throughout the Great Lakes System. The procedure specified in the final Guidance includes elements of both proposed Options A and B but has eliminated some of the more burdensome and confusing aspects of the proposed Guidance. The final Guidance provides a greater degree of flexibility than afforded by either proposed procedure, by allowing States and Tribes to adopt different implementation approaches while at the same time ensuring consistency by requiring States and Tribes to implement specific components of the procedure. Nothing in this section should be construed as authorizing mixing zones for BCCs that are prohibited under procedure 3.C of appendix F. These procedures are to be used, however, to determine the magnitude of any mixing zone allowed under procedure 3.C of appendix F.

Specific components of the proposal, comments on those specific components, and modifications in the final Guidance are discussed below.

a. Steady State vs. Dynamic Modeling

i. Proposal: In the proposal, both options envisioned that, in most instances, a simple, steady-state mass balance approach would be used to develop TMDLs, WLAs in the absence of a TMDL or preliminary wasteload allocation for the purpose of determining the need for WQBELs reasonable potential under procedure 5 of appendix F. A mass balance approach is a method used to approximate the mass of pollutants within a water body. It is based on the physical law of conservation of mass which dictates that mass cannot be created or destroyed but only transformed. This approach assumes that the input of mass into a system (e.g., through point and nonpoint source loadings, atmospheric deposition, groundwater seepage) equals the loss of mass from a system plus any losses due to transformation of mass within the system.

The proposal provided that the results of dynamic modeling be used only where the results can be shown to be more restrictive than the results due to the steady-state assumptions of both options A and B. EPA requested comments on whether the States should be allowed to use dynamic modeling regardless of whether the results are more or less stringent than results from using a steady-state approach.

ii. Comments: In general, commenters supported the use of dynamic modeling without the limitation that the results must be more restrictive than the results using steady-state assumptions recommended in both options A and B. Commenters pointed out that existing EPA guidance promotes the use of dynamic modeling and that the final Guidance should not contradict existing guidance by imposing new restrictions on the use of dynamic modeling.

iii. Final Guidance: EPA agrees with commenters and the final Guidance allows the use of both steady-state and dynamic models to support establishment of TMDLs. The final Guidance therefore retains provisions for using a steady-state, mass balance approach, but also allows the use of dynamic modeling regardless of whether the results are more or less restrictive than would be generated

under steady-state assumptions. For an in-depth discussion of available models, see EPA's Technical Support Document for Water Quality-based Toxics Control (TSD), EPA/505/2-90-001, 1991, available in the docket. EPA recommends that a model be selected based on its adequacy for the particular application. For example, adequacy of a model may depend on the type of pollutant (e.g., BOD/DO, toxics, etc.) or the type of waterbody (e.g., river or lake). Steady-state models compute average spatial profiles of constituents within a waterbody assuming that loadings, upstream water quality, stream flow rates, and meteorological conditions remain constant over time. Dynamic models predict both temporal and spatial variations in water quality due to varied loadings, flow conditions and meteorological conditions. Dynamic models are thus particularly useful for analyzing impacts that vary over time, such as loadings resulting from storm events and long term seasonal cycles. In determining whether to use a steady state or dynamic model, the cost of application, data requirements, the availability of historical data, and the availability of the particular model and model support need to be considered.

b. Stream Design Flows

i. Proposal: In the proposal, both options A and B specified the stream design flow under which criteria and values are to be implemented. Although most point sources discharge to continuously flowing streams, the amount of water available to dilute the discharge typically varies with the season and with periodic storms and drought conditions. Thus, in deriving TMDLs, wasteload allocations in the absence of TMDLs and wasteload allocations for the purpose of determining the need for WQBELs, it is necessary to establish the stream conditions under which applicable criteria and values will be implemented. The volume of water flowing through the tributary in a given time period at the design flow condition is the volume available to dilute all pollutants present or introduced into the water body and thus is a necessary factor in developing a TMDL, wasteload allocation in the absence of a TMDL, and a preliminary wasteload allocation for the purpose of determining the need for WQBELs using a steady-state model. The proposed Guidance specified different design flows for chronic aquatic life, acute aquatic life, wildlife, and human health criteria because of differences in how the criteria were developed. A detailed discussion of these flows and the basis for choosing these flows can be found in the preamble to the proposed guidance (58 FR 20933).

ii. Comments: Several commenters suggested that the restriction on stream low flow quantity for dischargers of non-BCCs is not scientifically defensible and recommended that EPA not specify design flows. Another commenter suggested that specifying design flows simply adds a further level of conservatism in TMDL development. They believe that this conservatism, coupled with the margin of safety (MOS) may result in overly stringent WLAs and LAs.

iii. Final Guidance: The final Guidance provides that the specified stream design flows be used as a default assumption in developing TMDLs, wasteload allocation in the absence of a TMDL and preliminary wasteload allocations for the purpose of determining reasonable potential, but allows the use of alternative stream design flow under certain conditions discussed below. The final Guidance adds new language clarifying that stream design flows are appropriate for TMDLs, wasteload allocations in the absence of a TMDL and wasteload allocations for the purposes of determining the

need for WQBELs established using steady-state models but are not likely to be applicable for those calculated using dynamic modeling.

EPA retains language from Option A that the loading capacity is initially calculated at the furthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of the appropriate criteria or value is determined by multiplying the criterion or value by the flow at the farthest downstream location in the tributary basin at the appropriate design flow condition. States could calculate the loading capacity at interim points in the basin. However, States and Tribes must include the total load capacity for the entire basin when establishing the TMDL. Even though the flow at the farthest downstream point on an effluent-dominated stream may be largely effluent, the loading capacity for the water in the stream is still the product of the criterion and the total flow in the stream.

The final Guidance specifies the 7-day, 10-year low flow (7Q10) or the 4-day, 3-year biologically-based design flow (4B3) for chronic aquatic life criteria or values; the 1-day, 10-year low flow (1Q10) for acute aquatic life criteria or values; the 90-day, 10-year low flow (90Q10) for wildlife criteria or values; and the harmonic mean flow for human health criteria or values. The final Guidance also stipulates that the lowest load is then selected as the loading capacity.

Although EPA received numerous comments suggesting that flows other than those specified in the proposal be adopted, none of the commenters supplied any scientific data supporting their proposed alternative flows. Many commenters supported the proposed flows. In the interest of promoting greater consistency among States and Tribes in the Great Lakes System, EPA is retaining, with the exception of the design flow specified for wildlife (see discussion below), the proposed design flows in the final Guidance. These design flows are default values that must be used in developing TMDLs, WLAs calculated in the absence of TMDLs, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of appendix F. EPA recognizes that in some instances, these flows may be overly conservative, or, in other situations, may not be protective enough. Thus, the final Guidance allows States and Tribes to use alternative stream design flows when data exist to demonstrate that such an alternative is appropriate for stream-specific and pollutant-specific conditions, such as using seasonal flows to obtain seasonal WLAs. Allowing alternative stream design flows is especially necessary when a dynamic model is used to calculate the TMDL. Dynamic models use the entire flow record, not just one design flow, in making TMDL calculations. States and Tribes may also adopt more stringent design flows than those specified here in accordance with section 510 of the CWA.

The criteria and values derived pursuant to the final Guidance are not designed to be never-exceeded values. Rather, EPA has determined based on scientific analyses that they may be exceeded at varying frequencies and durations without irreparable injury to human health, wildlife, or aquatic life. Current EPA guidance recommends stream design flows for chronic and acute aquatic life and human health (see p. 79 of the 1991 TSD). Until today, EPA has not implemented wildlife criteria, nor has it recommended a design flow for wildlife criteria.

iv. Wildlife

(A) Proposal: For TMDLs, WLAs calculated in the absence of TMDLs, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of appendix, based upon wildlife criteria or values, the hydrological-based, 30-day, 5-year low flow (30Q5) flow was specified in the proposed guidance. EPA also specifically asked for comments on using the 90-day, 10-year (90Q10) low flow, and the harmonic mean flow for wildlife criteria or values in the preamble to the proposal.

Both the 30Q5 low flow and the 90Q10 low flow include a factor representing the rate-limiting step between the exposure to the pollutant and the effect on the organism (30 days and 90 days, respectively). For wildlife, the rate-limiting step is chemical bioaccumulation. The 30-day and 90-day period were proposed as representing reasonable time periods for chemical bioaccumulation. The 30Q5 low flow and the 90Q10 low flow also include a value representing the rate at which the affected organisms recover (a 5 year and 10 year return frequency, respectively).

(B) Comments: Several commenters claimed that the proposed 30Q5 low flow is not scientifically defensible for wildlife criteria and asserted that the low flow should be the harmonic mean flow. Commenters suggested that it was inappropriate to use a short term low flow such as the 30Q5 and that the harmonic mean stream flow is more consistent with the long-term nature of bioaccumulation processes. Another commenter recommended the use of the 7Q10 low flow for implementing wildlife criteria.

One commenter pointed out that both the 30Q5 low flow and 90Q10 low flow are consistent with life cycles of small water mammals (otter and mink). Several commenters support the use of a 90Q10 low flow for the implementation of the wildlife criteria because it allows a reasonable time period for chemical bioaccumulation (90 days) with a reasonable return frequency (10 years).

(C) Final Guidance: The final Guidance only establishes wildlife criteria for BCCs (see section VI of this document). Therefore, the stream design flow specified in the final Guidance for wildlife criteria would apply when a mixing zone for a BCC is authorized under procedure 3.C.6 of appendix F.

The final Guidance specifies that a 90-day, 10-year low flow be used for the implementation of wildlife criteria in tributaries. This is the lowest 90-day average flow that would occur, on average, one year in every ten years based on a statistical review of historic flow data. EPA recognizes, as some commenters suggested, that a 30-day averaging period may be viewed as conservative for some pollutants, given the long time it may take for bioaccumulation. EPA agrees with commenters that a 30-day period is too short to represent bioaccumulation and is instead specifying the use of a 90-day averaging period when no data exist to suggest an alternative.

EPA disagrees with the commenter's recommendation to use the 7Q10 low flow for wildlife. As discussed in the preamble to the proposal, for wildlife, unlike for aquatic life, the impacts of

chemicals with a high propensity to bioaccumulate in aquatic organisms are of greatest concern because aquatic organisms comprise a major portion of the diet of many wildlife species. Because of the relatively slow rate of uptake by aquatic organisms of bioaccumulative chemicals, residues in the food chain have a delayed response to increases in ambient concentrations of chemicals during short-term periods, such as during low flow events. The Steering Committee thus judged a longer term averaging period to be more appropriate for wildlife than the 7-day averaging period used for aquatic life.

EPA recommends the 90-day averaging period for implementing wildlife criteria as a reasonable estimate that can be used to establish limits that are protective of wildlife. EPA suggests that the 90 day period is appropriate because concentrations of BCCs in the water column are not expected to fluctuate excessively; BCCs all have very high bioaccumulation factors (BAFs), and the toxicological data used to establish wildlife criteria are not based on acute effects. A 90-day averaging period also coincides with the length of seasons. Some studies have documented seasonal variability in fish tissue concentrations.

EPA agrees with the commenter's statement that the 10-year period represents a reasonable return frequency. EPA also agrees with commenters' suggestions that a five year return frequency is too short. EPA disagrees with commenters who recommended the harmonic mean be used. EPA believes that the harmonic mean is too long and may not be protective of shorter lived wildlife species. The harmonic mean may not be an appropriate proxy for wildlife because the lifespan of wildlife is highly variable and may be very short. The harmonic mean is used for the protection of humans with an average exposure of 70 years (e.g., an average lifespan), substantially longer than any of the wildlife species. In addition, wildlife criteria focus on reproductive endpoints, a subset of toxicological endpoints, to protect against population effects, while human health criteria cover a broad range of effects on individuals.

EPA believes specifying the 90Q10 low flow as a default and allowing the use of site-specific data balances the need for consistency while allowing the best scientific approach to be used. In response to comments that food chain effects attenuate the effects of fluctuations in ambient concentrations, the final Guidance will allow the use of an alternative stream design flow where data exist to demonstrate that such an alternative flow is appropriate for stream-specific and pollutant-specific conditions to be protective of wildlife. EPA recognizes that in some situations in the Great Lakes System, internal loadings of BCCs may dominate over external, or point source, loadings. These types of internal loadings (e.g., sediment resuspension) tend to be constant over long periods of time, and depending on local mass ratios, may buffer the fluctuations from point source loadings. However, because the design flow is an important parameter in establishing TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for the purposes of reasonable potential, it is important to specify a default value that is protective of wildlife in the absence of site-specific data. EPA recognizes the 90Q10 low flow may be conservative for certain pollutants for certain streams, and encourages dischargers to work with States and Tribes in generating site-specific data.

v. Chronic Aquatic Life

(A) Proposal: The proposal specified the 7-day, 10-year low flow (7Q10) or the 4-day, 3-year biologically-based design flow (4B3) for chronic aquatic life criteria or values.

(B) Comments: Several commenters supported the design flow for aquatic life criteria and noted that these stream design flows are consistent with EPA's 1991 TSD. One commenter agreed that for protection from chronic effects, the 7Q10 low flow is appropriate. Several commenters recommended that 30Q10 be used as an alternative. One commenter asserted that the 7-day, 10 year flow is overly conservative because the chronic water quality standards are based on toxicity tests of at least 24 days, and stated that the 30-day, 10- year low flow would be more appropriate.

(C) Final Guidance: Like the proposal, the final Guidance authorizes the use of either the 4B3 biologically-based design flow or the 7Q10 hydrologically-based design flow as the stream design flow for chronic aquatic life criteria. Unlike in the proposed guidance, however, the final Guidance also provides additional flexibility by allowing the use of an alternative stream design flow where data exist to demonstrate that the alternative is appropriate for stream-specific and pollutant-specific conditions. In the absence of such data, EPA continues to specify the 4B3 or the 7Q10 stream design flow to ensure protection of aquatic life from chronic effects.

The 4B3 is that flow, determined on a case-by-case basis, that would provide for an excursion of chronic aquatic life criteria, over a 4-day averaging period, only once every three years, on the average. This flow is selected because EPA has determined that criteria developed on that basis may be exceeded over a 4-day averaging period once every three years without injury to the aquatic ecosystem. (See 1991 TSD). A 4B3 flow can be calculated using the computer program DFLOW supported on EPA's computers at the National Computer Center in Research Triangle Park, NC. Further information may be obtained from Assessment and Watershed Protection Division, U.S. Environmental Protection Agency, 401 M St, S.W., Washington, D.C. 20460.

EPA also allows, as an alternative, the hydrological-based 7Q10 low flow. The 7Q10 is the lowest 7-day average flow expected to occur on the average one year in every ten, based on the period of record. Empirical data from approximately 60 streams show that the 7Q10 low flow provides a degree of protection approximately equivalent to the 4B3 flow. The U.S. Geological Survey routinely publishes statistics that commonly include estimates of the C for most riverain systems.

vi. Acute Aquatic Life

(A) Proposal: In the preamble to the proposal, EPA solicited comments on whether the final rule should specify a design flow for the purposes of implementing acute aquatic life criteria. The preamble discussed the recommended use of the 1Q10 low flow for acute aquatic life in existing EPA guidance (See the 1991 TSD, available in the docket).

(B) Comments: One commenter suggested that use of the 1Q10 low flow for acute aquatic

life criteria is too conservative and that the final rule should specify use of the 7Q10 low flow.

(C) Final Guidance: In the final Guidance, EPA specifies the 1Q10 low flow for purposes of implementing acute aquatic life criteria. This design flow would be used in determining whether the FAV cap is sufficient to protect against acute aquatic life effects. The 1Q10 low flow is consistent with the recommended design flow specified in existing EPA guidance (e.g., TSD). EPA agrees that this design flow may be overly conservative in some instances but this flow should be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. This is also consistent with the TSD, which recommends allowing for site-specific or chemical-specific conditions. States and Tribes may want to use the biologically based 1B3 as an alternative flow for acute aquatic life. The 1B3 is also discussed briefly in EPA's TSD. In addition, alternative averaging periods can be developed from data on the time course of mortality in acute toxicity tests.

vii. Human Health

(A) Proposal: In the proposal, EPA specified the use of the long-term harmonic mean flow to implement human health criteria.

(B) Comments: Several commenters supported the design flow for human health criteria and pointed out that it is consistent with existing EPA guidance. However, several commenters suggested that there was no scientific justification beyond the limited references in existing EPA guidance for using the harmonic mean instead of the arithmetic mean for human health criteria. One commenter suggested that the cost of statistically generating the harmonic mean statistic for the numerous surface water discharges in the basin could be prohibitive. The commenter also suggested that the harmonic mean flow estimate may be more error-prone than other flow estimates because statistics such as the harmonic mean flow are only useful where stream flow is highly variable. One commenter recommended the use of a mean annual flow as an alternative. Another commenter suggested that the 7Q10 low flow or 30Q10 low flow should be required rather than the harmonic mean flow.

(C) Final Guidance: The final Guidance retains the use of the long-term harmonic mean flow to implement human health criteria as supported by current EPA guidance. EPA has determined that such a level will ensure that criteria will not be exceeded under stream conditions that represent long-term average conditions. The harmonic mean flow is the sum of the reciprocals of individual flow measurements divided into the total number of individual flow measurements.

The harmonic mean was chosen as a design flow for human health criteria because human health criteria are designed to protect an individual over a lifetime of exposure. Human health criteria based on cancer potencies and risk levels are based on models which extrapolate animal data to a human lifetime. Similarly, a human non-cancer criterion is based on an R_dD (or ADE, as it is referred to in the final Guidance which is an acceptable daily exposure over a lifetime. Therefore, EPA has attempted to match the longest stream flow averaging period (using harmonic mean) with the criterion

which is protective over a human lifetime. EPA disagrees with the suggestion that an arithmetic mean rather than a geometric mean be used. For carcinogens, it is appropriate to determine the long-term mean exposure concentration. Because flow is not normally distributed, using the arithmetic mean flow for design purposes will underestimate the mean concentration. Using the downstream harmonic mean flow will more closely estimate the mean concentration.

In rare instances where a human health criterion or value is based on a short term toxicological effect (i.e., the critical effect upon which the criterion/value is based is significantly less than lifetime and may be an acute effect), the design flow should be adjusted accordingly. This does not pertain to ADEs (R_pDs) in which a short term study has been used as the ADE basis and an uncertainty factor has been used to account for less than lifetime study results. This pertains only to those situations where the critical effect is the short term effect and no additional uncertainty factor has been used to account for less than lifetime exposure. A good example of this is EPA's R_pD for nitrate. The critical effect, upon which the R_pD is based, is toxicity to children after a short term exposure. In this case, a harmonic mean would be an inappropriate design flow for such a short term effect. In this case, a 7Q10 or a 4Q3 design flow may be more appropriate.

EPA is setting the default design flow for human health as the harmonic mean. The harmonic mean can be calculated using the computer program DFLOW supported on EPA's computers at the National Computer Center in Research Triangle Park, NC. Further information may be obtained from Assessment and Watershed Protection Division, U.S. Environmental Protection Agency, 401 M St, S.W., Washington, D.C. 20460.

Because EPA recognizes that there may be situations, like those discussed above, where a different design flow is more appropriate, the final Guidance allows the use of an alternative design flow for human health criteria where data exists to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions.

c. Mixing Zones for Non-BCCs

i. Proposal: In the proposed guidance, Option A did not provide specific requirements for mixing zones for either chronic or acute criteria. Rather, under Option A, site-specific cross-checks would be conducted at each source location to ensure that water quality standards including acute and chronic aquatic life, wildlife, and human health, are attained at the edges of applicable mixing zones, or if mixing zones are not allowed under State law, throughout the basin. Option A did not specify the size of mixing zones but suggested that mixing zone requirements, if any, adopted by the various States will be used for the cross-checks.

Option B specified for both new and existing sources that WLAs based on acute aquatic life criteria shall not exceed the Final Acute Value (FAV) in order to ensure protection of aquatic life from acute effects. The provision is identical to the provision for Open Waters of the Great Lakes System. For WLAs based on chronic aquatic life, wildlife and human health criteria, Option B specified different requirements for new and existing sources. For existing sources, Option B provided a formula to

derive the dilution fraction based on the relationship of the effluent flow of the point source to the flow of the receiving waters and an assumption regarding how rapidly mixing occurs. The dilution fraction is the fraction of the 7Q10 that is available for dilution in the WLA calculation. Under the formula proposed in Option B, the dilution fraction varied from 10 to 25 percent. The proposed guidance allowed an opportunity to demonstrate that a larger mixing zone is acceptable subject to a mixing zone demonstration conducted in accordance with section E of proposed procedure 3B. This provision in the proposal specified that in no case could the dilution fraction exceed 75 percent. For new sources, option B specified that WLAs based upon chronic aquatic life, wildlife and human health criteria or values shall equal the criteria or values unless a mixing zone demonstration is provided, approved and implemented in accordance with proposed procedure 3B.E. The proposal also specified that in no case should the demonstration result in a mixing zone greater than the dilution fraction established for existing sources.

ii. Comments: Several commenters suggested that a dilution fraction of 25 percent is overly conservative based on the type and level of wildlife and human health exposure which are likely to occur and suggested the use of a larger fraction of the design flow for dilution.

Several commenters suggested that option A, by not establishing a dilution fraction and, in effect, allowing 100% of the design flow for dilution, does not provide sufficient margin of safety and is inconsistent with the Steering Committee's recommendation that only 10-25 percent of the design flow be allowed for dilution.

Several commenters suggested that Option B is inconsistent with the Steering Committee proposal, insofar as that proposal did not provide the increased mixing zone option to existing discharges of BCCs to tributaries. Only the default dilution was allowed (10-25 percent of design flow).

A number of commenters disagreed with the provision requiring differential treatment for new and existing dischargers of non-BCCs. Commenters suggested that new dischargers, like existing dischargers, should be able to adjust the mixing zone based on a mixing zone demonstration to a dilution fraction higher than the 10-25% default specified for existing dischargers in the proposal.

iii. Final Guidance: The final Guidance adopts the Option B provision that TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for purposes of reasonable potential shall not exceed the FAV, unless a mixing zone demonstration is conducted and approved pursuant to procedure 3.F of appendix F. This is intended to ensure protection of aquatic life from acute effects. The rationale described in the discussion of Acute Mixing Zones for OWGLS applies here.

In the final Guidance, for TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for purposes of determining the need for WQBELs based on chronic criteria to ensure protection of aquatic life, wildlife, and human health from chronic effects, the dilution fraction should be set at no greater than 25 percent of the appropriate stream design flow (e.g., for

aquatic life, human health or wildlife criteria). Unlike the proposal, the dilution fraction is established at 25 percent of the stream design flow rather than calculated using a formula. The final Guidance does retain the proposed provision allowing the opportunity to demonstrate that a larger mixing zone is acceptable subject to a mixing zone demonstration conducted in accordance with procedure 3.F of appendix F. Unlike the proposal, the final guidance allows the dilution fraction to go up to 100% if a mixing zone demonstration is completed and approved pursuant to procedure 3.F in appendix F. Procedure 3.F of appendix F requires a site-specific analysis of local conditions around the vicinity of the discharge to ensure that unacceptable impacts do not occur. If the information and analysis justifies a dilution fraction greater than 75%, as a general rule it should not be prohibited.

EPA is retaining 25 percent as the maximum dilution fraction unless a mixing zone demonstration suggests that an alternative dilution fraction is appropriate (i.e., in the absence of site-specific data). The 25 percent dilution fraction is consistent with existing EPA guidance. As described in the preamble to the proposal, the concept of the fraction of the stream design flow is based upon recommendations found in the Water Quality Criteria - Report of the National Technical Advisory Committee to the Secretary of the Interior, April 1968 (Green Book) and upon guidance from EPA's 1983 Water Quality Standards Handbook, both of which are available in the docket. The Green Book recommended that in order to prevent the initial mixing of point source wastewater from erecting a barrier to aquatic organisms, only 25 percent of the cross-sectional area of the river should be used for mixing. The Standards Handbook suggests that the value of 25 percent of total river flow is a rational estimate of the amount of river flow in 25 percent of the cross-sectional area.

This proposal is consistent with several States' current mixing zone policies. For example, Michigan uses a straight 25 percent of the stream design flow for all categories of criteria or values with an opportunity demonstrate for a larger percentage. Ohio uses a graduated scale for the dilution fraction that ranges between 10 percent and 100 percent of stream design flow. The use of a constant dilution factor as a default should support a more consistent permitting approach throughout the Great Lakes System. Flexibility is retained, however, by allowing an alternative mixing zone to be used when site-specific information and analysis support it (i.e., through a mixing zone demonstration).

EPA agrees with commenters and has removed the distinction between new and existing discharges for purposes of calculating TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for purposes of determining the need for WQBELs using chronic aquatic life, wildlife, and human health criteria and values. Under the final Guidance, for protection of aquatic life, wildlife and human health from chronic effects, TMDLs, WLA calculated in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F, shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration is conducted. In no case shall a State or Tribe grant a mixing zone which exceeds the area of discharge-induced mixing. This provision applies to both new and existing discharges of non-BCCs to tributaries. EPA suggests that while differential treatment for new and existing discharges is warranted for BCCs, because a primary goal of this initiative is to reduce loadings of BCCs to the Great Lakes, for non-BCCs, treatment of new and existing discharges will be the same.

7. Procedures for High Background Concentrations

a. Proposal: Under both Options, the proposal specified that when ambient water quality concentrations exceed narrative or numeric criteria or Tier II values, any discharge that has a reasonable potential to cause or contribute to an excursion above such a criterion or value should either be prohibited, i.e., WLAs set equal to zero, or a multiple source TMDL should be established that ensures the attainment of that criterion or value. Under both options, the procedures used in developing multiple source TMDLs for discharges were to be developed on a case-by-case basis, consistent with applicable State or Tribal regulatory requirements.

b. Comments: A number of commenters disagreed with the proposed approach to set WLAs equal to zero when background exceeds criteria because it would, in effect, force all point sources to achieve zero discharge. Commenters suggested that in addition to the use of multiple source TMDLs, EPA should make more use of readily available water quality variances, site-specific criteria, and intake credits in development of WLAs when background concentrations exceed criteria. Commenters suggested that the administrative burden of these existing mechanisms is a significant deterrent to using them. Commenters advocated a range of alternatives, from setting the WLA equal to the most stringent criterion up to setting the WLA equal to the background concentration of the receiving stream. Others suggested that WLAs be set at the greater of either the criteria or the background concentration.

Many commenters supported the use of multiple source TMDLs to prevent point sources from bearing a disproportionate share of the burden in achieving water quality goals when nonpoint source contributions dominate. Some commenters were concerned that developing multiple source TMDLs would be very resource intensive, and encouraged EPA to specify reasonable limits in the interim while TMDLs are developed.

c. Final Guidance: In response to numerous comments disagreeing with the proposal to set WLAs equal to zero when background exceeds criteria, EPA has removed this provision from the final Guidance. EPA first and foremost recommends developing TMDLs to address discharges to non-attained waters. However, EPA also recognizes the multitude of factors that need to be considered in the absence of a TMDL when background water quality concentrations exceed chronic narrative or numeric criteria, or Tier II values.

When uncertainty regarding loadings and load reductions are a consideration, a phased approach to TMDL development may be appropriate. For a more extensive discussion of multi-source, multi-media TMDLs, see the introduction to section VIII.C in this document. Permitting decisions for discharges to non-attained waters are addressed more fully in the provisions and accompanying supplementary information document discussion for eliminating mixing zones for BCCs (section VIII.C.4), considering intake water pollutants (section VIII.E), and in the supplementary information document discussion on the basis for developing WQBELs at section VIII.E.2.h.

8. Pollutant Degradation

a. Proposal: Both Options A and B allowed TMDLs to account for degradation of a pollutant provided two conditions were met. The first condition was that the regulatory authority must have information regarding the rate of degradation of the pollutant in the form of field studies or other relevant information. As discussed in the preamble to the proposal, field studies, if used, must document that degradation of the pollutant will occur under the full range of critical conditions expected to be encountered, and should quantify the degradation. Critical conditions should include the design conditions that are established for the implementation of criteria in ambient waters as well as other conditions such as periods of stratification of the water body and variability of the facility effluent flow rate. The preamble to the proposal also indicated that if field study information was not available, the regulatory authority could use other relevant information such as literature references from similar sites. Regardless of the type of information used, all information would have to be reviewed by the regulatory authority and found to be scientifically valid.

The second condition was that the studies take into account factors other than pollutant degradation that may affect the concentration of the pollutant in the water column including but not limited to resuspension of sediments, speciation and transformation.

b. Comments: Several commenters supported the procedures that provided for consideration of the environmental fate of a pollutant in the development of TMDLs. One commenter suggested that fate and transport should be considered in the development of TMDLs whenever suitable data such as existing literature or field data from similar sites are available. One commenter suggested that EPA should direct States to gather site-specific information in scientifically sound studies. Another commenter suggested that the regulatory agencies be responsible for collecting the necessary data.

Several commenters suggested that the final guidance specify that losses from the water column due to physical transfer to other media (i.e., through volatilization, bioaccumulation, sorption to sediments) are not acceptable fate processes for increasing TMDL allocations, since the pollutants may ultimately be re-released to the water column. Other commenters suggested that no transport processes should be precluded from consideration in the development of TMDLs and WLAs. One commenter suggested that pollutant degradation should not be accounted for unless rigorous studies concerning sediment re-suspension, speciation and transformation are also incorporated into the calculations.

One commenter suggested deleting the section on pollutant degradation from the final Guidance because it was not discussed in enough detail by the technical work group.

One commenter fully supported consideration of degradation and transport outside the mixing zone. The commenter recommended that existing EPA guidance such as Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals (May 1992) be used.

c. Final Guidance: The final Guidance retains the provision that TMDLs, wasteload allocations in the absence of a TMDL and wasteload allocations for purposes of determining the need

for WQBELs should be based on the general assumption that a pollutant does not degrade. Like the proposal, however, it also allows degradation to be taken into account on the basis of information from scientifically valid field studies or other relevant information, including the results of properly calibrated water quality modeling.

Each of the Great Lakes States has already adopted a narrative criterion specifying that waters shall be free from pollutants that settle to form objectionable deposits. EPA's existing NPDES requirements (40 CFR 122.44(d)) require establishment of permit effluent limitations to meet these narrative and other criteria. Upon adoption by States and Tribes or promulgation by EPA, general condition 6 in the final Guidance requires that TMDLs prevent the accumulation of pollutants in sediments to levels causing impairment of designated or existing uses. Inclusion of this provision in the final Guidance reflects EPA's concern about sediment quality in the Great Lakes System and a recognition that it may often need to be considered.

EPA is currently developing new methods for preventing sediment contamination. The first step is to develop numeric sediment criteria guidance. Once a State adopts sediment criteria into its State water quality standards, regulatory authorities will need to factor such criteria into the TMDL and NPDES permitting process, in addition to applicable narrative criteria pertaining to the formation of objectionable deposits.

To the extent that volatilization does not represent a permanent loss from the Great Lakes System, current atmospheric loadings of volatile pollutants will be accounted for in determining background concentrations. In fact, atmospheric transport and degradation processes will influence the amount of volatiles available for re-entrainment in the water. Accordingly, volatilization losses can be considered when setting TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for the purposes of determining the need for WQBELs. It would be extremely difficult to establish a significant loss of ambient pollutants as a result of bioaccumulation. The confounding factors, including the potential loss of pollutants from the water column by bioaccumulation into plants, invertebrates, fish tissue biodegradation via depuration are not expected to be quantifiable enough to meet the second condition of biodegradation.

9. Mixing Zone Studies

a. Proposal: Option B allowed any interested party to prepare a mixing zone demonstration and allowed the permitting authority to modify the dilution fraction described above in accordance with such studies. Proposed procedure 3B.E described several required elements of a mixing zone study, all designed to address the area of mixing that can be allowed consistent with attainment of water quality standards.

b. Comments: Commenters raised questions about specific components of the mixing zone demonstration requirements. Several commenters questioned the requirement for documentation of the substrate and geomorphology of the mixing zone. Other commenters suggested that the analysis of attraction of organisms to the mixing zone is difficult to assess or predict. Another commenter

questioned the requirement to determine whether the habitat supports endemic species or naturally occurring species, and asserted that it is essentially a useless exercise. The commenter suggested that by definition, the surface water into which the discharge occurs will support whatever aquatic organisms inhabit the area, and whatever species is protected by the criteria may be present and may pass through the mixing zone.

c. Final Guidance: The final Guidance adopts the mixing zone demonstration language as the alternative to the mixing zones specified for both OWGLs and tributaries. The language has been modified to require consideration of potential impacts to threatened and endangered species consistent with the Endangered Species Act and otherwise to enhance clarity. The mixing zone demonstration provision provides flexibility to allow a greater dilution fraction than otherwise provided in sections D and E, as well as an exceedance to the FAV cap, to better reflect site-specific considerations.

EPA believes that characterizing the substrate and geomorphology of any potential mixing zone site is necessary to characterize potential impacts on water quality. Similarly, the effects of any potential mixing zone on endemic or naturally occurring species must also be considered. EPA recognizes that dischargers may be required to collect additional data and perform additional analyses in order to qualify for a mixing zone exception; however, EPA believes it is reasonable and appropriate to require this information if dischargers wish to use values greater than the default values specified.

10. Pollution Trading Opportunities

As described in the proposal, the TMDL process provides an opportunity for pollution trading in the water quality program as long as CWA goals and requirements are met. Effluent limits and nonpoint source controls, for example, must be designed, maintained and enforced so that water quality standards and other statutory and regulatory requirements are met. For purposes of the final Guidance, trading refers to approaches which introduce market incentives into water quality control decisions by acknowledging the ability of a point source to achieve water quality-based loading reductions through creative, enforceable market mechanisms.

The Guidance encourages States to look for pollution trading opportunities as TMDLs are established. However, trading opportunities may be limited by the general conditions and specific requirements (e.g., mixing zones for BCCs) that apply to all TMDL development.